Nova Southeastern University
Institutional Review Board
Manual for Research with Human Subjects

Revised: December 2009
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Chapter 1: History and Purpose

Introduction

Nova Southeastern University (NSU) encourages research and scholarship in and among its colleges and centers and in collaboration with other educational institutions, agencies, and organizations. In this regard, the university, while respecting the right of faculty to full academic freedom in research, is firmly committed in adhering to the basic ethical principles underlying the acceptable conduct of research involving human subjects, as set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. These three principles, respect for persons, beneficence, and justice, are relevant particularly to the protection of human subjects in biomedical and behavioral research, and are the accepted requirements for the ethical conduct of such research.

- Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
- Beneficence entails an obligation to protect persons from harm by maximizing anticipated results and minimizing possible risks of harm.
- Justice requires that the benefits and burdens of research be distributed fairly.

Moreover, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to minimize risks; and the principle of justice requires that subjects be fairly treated.

The university has set standards for the conduct of research that mandate well-conceived and well-conducted research. To assist in maintaining those standards, an Institutional Review Board (IRB) has been established, and this *Policy and Procedure Manual for Research with Human Subjects* has been prepared for distribution to the university community. The manual provides detailed information to support institutional initiatives for guaranteeing compliance with federal regulations governing the protection of human subjects and to guide principal investigators in procedures relevant to the development of research protocols that include human subjects. Throughout this manual, humans whose 1) physiologic or behavioral characteristics, 2) understanding of their lived experiences, and/or 3) responses are the object of study are referred to as subjects; however, the university in no way intends to demean the humanity and individualism of such persons. Recognizing that regulations and policies and procedures are no guarantee of ethical conduct, it is the responsibility of individual researchers to make ethical considerations central in the conduct of research and to have a clear understanding of their duties to human subjects.

This *Procedure Manual for Research with Human Subjects* was developed under the direction of the Institutional Review Board Task Force established by the university's Executive Provost and Vice President for Academic Affairs in May 1996. Special recognition and thanks are extended to the members of the Task Force for their commitment of time and significant contributions to the development of this document. The manual was updated in 2003 because of changes in institutional policies and
procedures as well as policies and procedures arising from the implementation of the Health Insurance Portability and Accountability Act (HIPAA) regulations effective April 14, 2003. In 2007, this manual was revised again providing direct links to many of the NSU IRB’s policies now available on its Web site. Researchers are encouraged to visit the Web site at http://www.nova.edu/irb/manual/policies.html for the most current policy information.

Responsibility

IRB Responsibility
The Nova Southeastern University Institutional Review Board (NSU-IRB) was established to respond to The National Research Act Public Law 99-158, and continues to function in response to the most recent extension of that law, The Health Research Extension Act of 1985. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has set forth guidelines, specifically, the Belmont Report and Title 45, Part 46 of the Code of Federal Regulations, to guide research with human subjects and ensure their protection in the design and conduct of research.

These federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that such research is reviewed and approved by the university’s Institutional Review Board. The university’s administration has made the decision that all research with human subjects, whether funded or unfunded, or subject to federal regulation or not, will be reviewed and approved in accordance with the guidelines set forth in this manual.

The IRB is responsible for determining and assuring, under the auspices of NSU faculty, staff, and students, that:

- the welfare and rights of human subjects are adequately protected and informed consent given, if necessary;
- human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research;
- the necessity and importance of the research outweighs the risks to the subjects;
- the researcher(s) is/are qualified to conduct research involving human subjects.

Investigator Responsibility
Information related to the general responsibilities of investigator’s may be found here: http://www.nova.edu/irb/manual/forms/general_responsibilities_investigator.pdf
Chapter 2: IRB Policies

Policies related to the following areas are available at the NSU IRB’s Web site at:  
http://www.nova.edu/irb/manual/policies.html

Policies and Procedures

Part I – IRB General Information  
* Federal Wide Assurance  
* IRB Authority  
* IRB Membership

Part II – IRB Meetings and Operations  
* IRB Record Requirements  
* IRB Meeting Operations  
* IRB Levels of Review and Decisions  
* Appeal of IRB Actions/Determinations  
* Monitoring of Approved Research, Approval Duration, and Continuing Review  
* Suspension and Termination of Research  
* Unanticipated Problems and Adverse Event Reporting  
* Amendments to Research  
* Verification of Compliance with Approved Protocols From Sources Other Than Investigators  
* Further Review/Approval of IRB Actions  
* Changes to Policies  
* Noncompliance

Part III – Investigator Responsibilities  
* General Responsibilities of the Principal Investigator  
* Informed Consent  
* Financial Conflicts of Interest with Respect to Sponsored Projects

Part IV – Education and Training  
* Human Subjects Research Training

Part V – General Research Items  
* Research with Children  
* Research with Prisoners  
* Research with Pregnant Women, Neonates, and Fetuses  
* Student Research  
* Research Conducted with Students as Subjects
Part VI - HIPAA
*HIPAA Research Policy No. 1: General
*HIPAA Research Policy No. 2: IRB Waiver of HIPAA Authorization
*HIPAA Research Policy No. 3: De-identified and Decedent Information
*HIPAA Research Policy No. 4: Reviews Preparatory to Research
*HIPAA Research Policy No. 5: Accounting of Disclosure
*HIPAA Research Policy No. 6: Guidance on Research at Outside Entities

In addition to the polices noted above, the following are also applicable.

Research Subject to Review
To comply with the federal guidelines covering the protection of research subjects, and to ensure appropriate ethical management of research programs conducted by NSU faculty, staff, and students, all funded and unfunded research proposals involving human subjects fall within the jurisdiction of the IRB. This includes all research activities conducted by any student or any employee of NSU that involves human participants in any manner or involves records about clients, students, or employees. Such research activities must be reviewed by the IRB before any research may begin. However, there are multiple levels of review that depend upon the nature of the research, the populations involved, the potential for harm, and the potential for violation of confidentiality rules which control the level of the review. If additional information/clarification is necessary, the IRB Chair, IRB Administrator, or the Office of Grants and Contracts should be contacted.

The Center Representative is responsible for determining the level of review that applies to a given research project. The levels of review are discussed in the next chapter. The three possible levels of review include: Center Level Review, Expedited Review, and Full Review. While these guidelines are intended to give a researcher some expectation of the level of review needed, a representative of the IRB must determine the actual level of review for each project. The Center Representative is authorized to consult with the Chair and/or other members of the IRB about the type of review necessary for a protocol.

Auditing of studies
The university and the IRB reserve the right to request that studies be audited for compliance with university policy and regulations governing human subjects research. Investigators should also be aware that federal regulatory agencies that govern research with human subjects (Department of Health and Human Services and the Food and Drug Administration) may also audit studies when appropriate. Consent procedures/documents must be sure to communicate to prospective subjects that all documentation pertaining to a study may be audited by regulatory agencies. The IRB also reserves the right to observe, or have a third party observe, the informed consent process of all approved research.

Concerns Expressed by Subjects
Subjects should be reminded that concerns and/or complaints about research they are
participating in should be directed to either the investigators and/or the IRB. Concerns/complaints received by the IRB will be investigated promptly, and reported to institutional officials as well as any applicable regulatory agencies.

**Closing Reports**
PIs are responsible for submitting closing reports to the NSU IRB for all studies approved at the Expedited or Full Review levels with 30 days of the conclusion of research. Research is considered closed at the time when work with human subjects AND data analysis have ceased. The closing report is submitted via the NSU IRB Closing Report Form (see Appendix F).
**Education versus Research**

I. Case Studies

It is sometimes unclear whether the presentation of one or more case studies constitutes education or research. It is generally well accepted that case–study presentations made in classroom settings or in the on-line equivalent of a classroom setting constitute education. Such cases need to follow regulatory privacy rules (HIPAA and FERPA) for consent and require use of the NSU Disclosure for Educational and Related Purposes Form. A form is not required if the case meets the HIPAA definition of being fully de-identified but is always necessary in cases where the client could be identified by data, pictures, voice recording, demographics, or other information which is presented to the audience.

There are, however, other situations where the line between the educational and research use of case studies is less clear. This is important because both NSU and federal regulations require different procedures for each use. Federal regulations define research as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” When research is involved, IRB approval must be obtained and consent forms must conform to research guidelines.

The difference between education and research use is often the intent of the user of the case information. When the intent is simply to present a single case or a series of cases without generalizing or studying the results, this is usually considered an educational presentation whether it is presented in a classroom or at a workshop or conference. However, when the intent is to generalize beyond the case to general recommendations, procedures, or conclusions, the intent is usually considered to reflect research. In most cases, single case study presentations are classified as education, while presentations which aggregate data from multiple cases are research. However, there are significant exceptions to these rules and they cannot be seen as absolute.

These cases do not deal with more organized research, where data are collected specifically to test a hypothesis or idea, but rather when data are collected after the fact from cases that follow the general clinical protocols for a specific practice area. In situations where additional measures or non-routine techniques are used with a client for the purposes of evaluation, then the case must be considered research no matter how many techniques are involved. However, in all cases where there is any question we request NSU personnel contact their center/college IRB Representative (http://www.nova.edu/cwis/ogc/irb/) or the Office of Grants and Contracts directly.

A. Single Case Presentations

In general, material collected from clients which is used only in educational settings (broadly defined to include traditional classrooms as well as distance and Internet learning sites) with the purpose of training students or attendees in specific clinical processes (diagnosis, recognition, and/or treatment) is being used for educational...
purposes. This material usually consists of case studies used to illustrate rather than to support the primacy of one technique over another; although, the teacher may eventually share such conclusions with the students.

There are two primary exceptions regarding single cases as educational presentations. The first exception is when a single case is used as its own control so that generalizable results can be granted. The second arises when a case is deliberately given additional measures to prove the efficacy of a technique or process.

Presentation at conferences outside of the educational setting tends to be a gray area, but the same reasoning applies: presentation of one or more individual case studies for the purposes of illustrating a specific diagnosis, diagnostic method, or treatment approach remains an educational pursuit.

Some examples of single case determinations include the following:

- Presentation of a case (in class, a conference, or in print) where auditory steady-state evoked potentials were used to estimate threshold to illustrate how steady-state evoked potentials data are used clinically when conducting pediatric hearing aid fitting (Education). However, if the case was presented to prove the superiority of the method at a conference or in a publication, then the case presentation would constitute research.

- A Grand Rounds presentation where a patient with a specific diagnosis is presented to illustrate diagnostic and treatment techniques for such a case. (Education)

- A case presented to illustrate a diagnostic or therapeutic method in a class, workshop, or conference. (Education)

- The client is given the routine test for a given disorder. S/he is also given a new, experimental procedure that is faster and cheaper. The case presentation focuses on the comparison between the two techniques. (Research)

- The client is given a behavioral treatment for hair pulling. The treatment is given in alternate months to see if the hair pulling returns in the months when the treatment is not given. The case study focuses on the differences between the months on and off the treatment. (Research) However, if placing the patient on and off the treatment was part of the routine clinical treatment of the disorder (such as medications which are given in cycles, then the case presentation would be of a routine procedure and not represent research).

- Using a case study to teach peers at a conference how to use a new type of splint. A case study is presented along with clinical data on functional outcomes with this splint when the data collected are those that are routinely collected in clinical practice. (Education).
• Case study of the new splint with additional outcomes measurement data not typically collected in your clinical practice OR collected and reported in more depth than is typical in one’s clinical practice. Collecting additional data is research. While quoting client/patient responses in normal documentation may be customary, systematic and in-depth collection of specific aspects of client/patient response is research. (Research)

B. Multiple Case Presentations

When cases are aggregated to prove the efficacy of a given method or procedure, to compare methods or procedure, or to describe certain demographic or therapeutic trends, the presentation is considered research. It should be noted that as long as de-identified data is used in such presentations, a Center Level Review, rather than a more extensive IRB evaluation, is likely. Most studies where patient data are aggregated are research even if it is only descriptive. Research is clearly conducted when a clinician exposes a client to experimental or altered techniques for the purposes of evaluating those techniques or methodologies.

The general exception is when the individual presents multiple single case studies, which by themselves would be considered single case educational studies. In such a situation, the multiple cases are not being aggregated but rather presented sequentially to illustrate clinical points. However, if at the end, the cases taken together are used to reach a generalization (such as one procedure or one demographic characteristic lead to more success), then this becomes research when presented outside the classroom situation at a conference or in a publication.

Some examples of multiple cases include the following:

• Aggregated case studies of the new splint as compared to a different type of splint. (The comparison implies efficacy research). (Research)

• Two case studies, one with the new splint and one with the traditional splint, presented to illustrate the two alternative approaches. (Education)

• Clients are randomly assigned to the new and traditional splint and evaluated for outcome. (Research)

• Comparison of cases of the steady-state evoked potential results to tone-burst auditory brainstem response data or to behavioral threshold data (implies validation or comparative research). (Research)

• Analysis of the efficacy of auditory steady-state evoked potential in aiding hearing aid fitting in three cases. (Research)

• A teacher uses a series of case vignettes to illustrate the strengths, weaknesses,
and pitfalls of alternate treatments in the field. The presentation is limited to classroom settings or the equivalent. (Education)

- A teacher uses a series of case vignettes to illustrate the strengths, weaknesses, and pitfalls of alternate treatments in the field at a conference or in publication. The presentation reaches conclusions about what is the best approach to practice in the area. (Research.)

- Presentation at a conference of how three different mental health cases were treated and the outcome is routinely used in the clinic. (Education)

- Presentation at a conference of how three different mental health cases were treated using special outcome measures chosen for the presentation. (Research)

- Presentation at a conference of how three different mental health cases were treated and the outcome. The clinician reaches conclusions about what demographic characteristics predict success in the clients. (Research)

II. Student Research Activities

A. Classroom Projects/Assignments

Research conducted by students, graduate or undergraduate, as a part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to or likely to lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis).

While most assignments for class do not require IRB review, some do as a result of the vulnerability of subjects or the potential risk to subjects including:

- Studies in which children will be interviewed or surveyed.
- Studies in which children are being observed, and data collected, where the investigator is also a part of the activities being observed.
- Studies involving prisoners, the mentally disabled, or pregnant women.
- Studies that ask subjects about illegal activities and which place the data at risk for subpoena and/or the subject at risk for loss of civil liberties.
- Studies in which subjects are at risk of breach of confidentiality, such as ones that ask sensitive or intrusive questions about behaviors.
- Studies that place subjects at risk due to emotionally charged subject matter.

Instructors are advised to discuss these issues with their students and clarify the role of the IRB should the student be interested in pursuing a research activity that might necessitate IRB review. Instructors should contact their center/college’s IRB Center.
Representative for more information. Center Representative contact information may be located on the IRB website (http://www.nova.edu/irb/).

Instructors are expected to review the proposed research to determine if it meets the definition of student research and is permissible under these guidelines. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believe that, under our guidelines, IRB approval is required, the instructor shall present for IRB approval one application setting forth the information requested within IRB documents.

Student researchers should also note that if there is any likelihood that the results of the project might want to be later used for research that does lend to generalizable knowledge (for example, within a dissertation or a presentation to a group other than the class), IRB approval must be secured prior to conducting the research activities. IRB approval cannot be granted retroactively. It is expected that any data collected as a class project will be destroyed after the grading of the project has been completed.

B. Thesis

Thesis and dissertations projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the IRB (beginning with the Center Representative of your college/school). Information related to the IRB process is available on the IRB website and Procedures Manual.
Chapter 3: Procedures/Process  
Step-by-Step Process

All research studies involving human subjects are reviewed in one of three ways, Center Level Review (previously labeled Exempt Research), Expedited Review, and Full Review. Every research protocol begins with a complete submission to the principal investigator’s respective Center Representative. This individual is charged with reviewing the submission to determine the appropriate level of review for the study as well as assuring that all necessary documents are included. Examples of studies falling into the different types of reviews are found later in this manual.

The Center Representative works with the primary investigator to prepare the required IRB documents in accordance with NSU policies/procedures.

At a minimum, all studies submitted for IRB review must contain a completed NSU-IRB New Protocol Form.

Additional items which may need to be included are:
- Informed consent forms
- Completed informed consent form checklists
- Evidence of approval by cooperative IRBs at other sites
- Data collection instruments
- Certification of translation for consents or instruments to be used with non-English speaking subjects
- Brochure/recruitment materials

Effective December 10, 2009 the IRB no longer reviews separate HIPAA Authorizations for Use and Disclosure of Protected Health Information in Research.

Once a submission is determined as complete, it is submitted to the Center Representative who is the starting point for the IRB process.

- If the study does not require Expedited or Full Review, the Center Representative will indicate that the study is exempt from further review after all documents are in order. All Center Level reviewed protocols are submitted to the IRB office via the NSU-IRB log system with a copy of the protocol and all supporting documents submitted to the IRB office via hardcopy for recording and archiving. The Center Representative notifies the principal investigator in writing of the determination of exemption and completes the Center Level Review Decision Form.
- If the protocol requires an Expedited Review, the Center Representative will forward a complete submission to the Office of Grants and Contract (OGC). The Expedited Review is conducted by the IRB Chair or his/her designee. Please note studies from the Health Professions Division as of December 1, 2006 will no longer need to be submitted to the HPD Research Committee before they are submitted to the NSU-IRB. Both processes will now run separately. The PI will
still require both HPD and IRB approvals to conduct a research project. NSU’s IRB will notify the Chair of the HPD Research Committee once the protocol is approved. Individuals within HPD should check with their respective center representative.

- If the protocol requires a Full Review, the Center Representative will work with the principal investigator to assure that all documents are in order and will then ask that the principal investigator provide 23 copies (and one original) of the complete IRB submission.
  - In addition, one copy of all research instruments to be used in the study (questionnaires, interviews, surveys, etc.) must be included. The 23 copies (and one original of the submission and instruments) will then be forwarded to the Office of Grants and Contracts. Upon receipt of all required paperwork, the Office of Grants and Contracts logs the IRB submission, assigns a protocol number, reviews it for completeness, forwards all copies to the IRB members, and places the protocol on the agenda for the next IRB meeting. Any revision requests by the IRB will be sent to the primary investigator via United States postal mail (or campus-wide Interoffice Mail for university faculty/staff). Once IRB approval is granted, the Office of Grants and Contracts notifies the principal investigator and in the case of funded research the appropriate agency.

Please note studies from the Health Professions Division as of December 1, 2006 will no longer need to be submitted to the HPD Research Committee before they are submitted to the NSU-IRB. Both processes will now run separately. The PI will still require both HPD and IRB approvals to conduct a research project. NSU’s IRB will notify the Chair of the HPD Research Committee once the protocol is approved. Individuals within HPD should check with their respective center representative.

The IRB conducts continuing review of all research, funded or unfunded, in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk, but not less than once per year for the life of the project. Federal regulation requires that IRB approved research be reviewed by the IRB by no later than one year from the date of approval—or sooner if the IRB determines that the nature of the research warrants shorter review intervals. No study may continue beyond the one-year approval until the IRB has reviewed the continuation request (see Appendix D). Researchers are also reminded that the IRB may conduct audits at intervals sooner than continuing review periods.

On the next page a flow chart summarizes the IRB process from the moment of initial protocol submission until an IRB decision is made.
SUBMISSION AND REVIEW PROCEDURES

Principal investigator (PI) develops research protocol for submission. (For research conducted at HPD, follow HPD research guidelines.)

Center representative conducts initial review.

Decisions: center level review—exempt from further review

Center representative logs submission and determination.

Decision is communicated to PI

Complete protocol file is transmitted to Office of Grants and Contracts.

For funded projects: Office of Grants and Contracts notifies funding agency of IRB approval.

For HPD protocols, IRB notifies HPD Research Committee chair.

Decisions: requires further review—either expedited review or full review

Center representative logs submission and determination.

Center rep. indicates expedited review, submits protocol to IRB Office.

IRB chair or designee reviews protocol.

In addition to the complete original protocol, 2 copies of the protocol, consent documents, recruitment materials, and all other supporting documents (except test instruments) must be included. Only one set of test instruments is necessary.

Center rep. indicates full review on submission form. PI or center rep. transmits complete protocol to IRB Office.

IRB reviews full review protocol.
Review of Research Forms

For all research involving human subjects, the principal investigator is responsible for completing the NSU-IRB New Protocol Form (Appendix A). Common attachments include a copy of all proposed consent forms, any advertising material intended for recruiting subjects, copies of all data collection, survey and test forms, and authorization/approval from IRBs/appropriate personnel at cooperative research sites (if the study is being conducted at sites other than NSU). If the cooperative site does not have an IRB, a statement of willingness to participate must be included.

The NSU-IRB New Protocol Form contains contact information, basic information about the proposed subjects in the study, certain procedures (such as payment to subjects), questions about protected health information, and whether translation is required of consent forms. Certain key issues should be remembered:

- Starting date indicated must allow time for the IRB to review the proposal and respond and thus cannot be the day the application is submitted or shortly thereafter. It cannot be the date of the IRB meeting, as this does not allow for response. An investigator may list “Upon IRB approval” as the starting date.

- Any research in which the principal investigator is a student must have a co-investigator who is a faculty or professional staff member.

- All researchers/investigators must have completed the NSU-designated human subjects research training (CITI Program) prior to submitting for IRB review.

- All items must be filled out. If Not Applicable to your study, write “NA”.

- If a cooperative research project has multiple sites attach additional page(s) as needed to list sites.

- The completed IRB submission is given to the primary investigator’s Center Representative who forwards it to the IRB office after all documents are checked and the submission is confirmed as complete.

- Check to determine whether any Protected Health Information is included in the study. This is information taken from patient records of any kind that are part of a HIPAA covered entity. At NSU, this includes all of the NSU Clinics. Information that is gathered directly from subjects is not PHI even though you may ask for information from the subject that is in the patient record.

The principal investigator is also responsible for submitting an NSU-IRB Continuation/Renewal/Revision of Approved Studies Form (see Appendix D) if he/she is seeking an extension of the IRB approval of the study or needs to make revisions to an already approved study.
• Researchers are reminded that IRB approval is granted for no more than one (1) year (or less, if the board determines that a study must be seen before the 12-month deadline) and that the IRB office must receive a completed Continuation/Renewal/Revision form no later than one month prior to the date of expiration of IRB approval.

• No research activities may continue past the date of expiration of the IRB approval (one year from the date of the approval letter) until the IRB has reviewed and approved the continuation.

• No revised protocol procedures may occur unless the IRB has approved the proposed changes. In addition, investigators should note that a change in procedure may alter the type of review needed for approval by the IRB. For example, a study that was approved at the Expedited Review level adds the collection of sensitive information from prisoners, thus the study would now require a Full Review.

Types of Review and IRB Actions

Information related to types of review and IRB actions may be found here: [http://www.nova.edu/irb/manual/forms/levels_of_review_and_decisions.pdf](http://www.nova.edu/irb/manual/forms/levels_of_review_and_decisions.pdf)

Cooperative Research

Cooperative research projects are those that involve more than one institution (non-NSU hospital, public school district, DCF, etc.) and can be designed to be both multi-site and multi-protocol in nature. In the conduct of such projects, each participating institution is responsible for safeguarding the rights and welfare of human subjects and complying with all regulations.

Institutional Approval

In cases where the research project will be housed and conducted at another institution with participation by NSU faculty, staff, or research participants, it is required that documentation of the primary institution's IRB approval and a copy of the research protocol and consent forms be obtained and made part of the NSU IRB records. The proposed research project must then go through an additional review by and receive approval from NSU's IRB. All cooperative research projects involving NSU faculty, staff, or research participants, whether conducted at NSU or off-site, must have NSU IRB approval.

Assurances

It is the responsibility of the lead institution to file the required assurances and certifications with the Office of Human Research Protections (OHRP). All assurances and certifications will be handled by the Office of Grants and Contracts.
Continuation (Continuing Review) or Amendments of Approved Research

Information related to continuation or amendments of approved research is available at the NSU IRB’s Web site:

Continuing Review:  

Amendments:  

Conflict of Interest

As documented previously in this manual, IRB members who may have a perceived conflict of interest with a study under review will excuse themselves from discussions related to the study. In addition, the university IRB is responsible for examining any possible conflict of interests investigators may have as they relate to human subjects. The NSU-IRB New Protocol Submission Form (see Appendix A) asks the primary investigator or any co-investigators to disclose any potential conflict of interest. It is also the responsibility of investigators to provide such information in consent forms as this information may affect a subject’s decision to be a participant in the study.

Adverse Events and Unanticipated Problems

Information related to the IRB’s policy on Unanticipated Problems and Adverse Events found at [http://www.nova.edu/irb/manual/policies.html](http://www.nova.edu/irb/manual/policies.html). The PI must also report the adverse event/unanticipated problem via the Adverse Events and Unanticipated Problems report form (see Appendix I). PI’s are also responsible for reporting adverse events/unanticipated problems to a study sponsor/funding agency and all applicable regulatory agencies. An IND Safety Report must be submitted when a serious adverse event may be related to a drug study and was not expected.
Chapter 4: Federal Privacy Legislation

HIPAA

Introduction:

Federal privacy regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) of 1996 went into effect April 14, 2003. The privacy regulations set forth requirements for the use and disclosure of protected health information (PHI) in research.

NSU has implemented a series of policies with regard to HIPAA and research. These policies apply to: (1) all NSU covered health care clinics and departments that allow access to PHI by researchers for research; and (2) all researchers. Researchers must refer to these policies to determine their responsibilities related to HIPAA compliance. Researchers will have other responsibilities related to human subject research, including compliance with the Common Rule. In addition to this policy, researchers will need to consult with NSU’s IRB policies and procedures related to the Common Rule to determine when and how to obtain IRB approval for a project and when and how to obtain informed consent.

Regardless of the relationship of the NSU researcher to NSU (e.g., faculty, adjunct, staff, student, resident or fellow) and to other entities outside of NSU (e.g., faculty and/or student at a teaching affiliate site), the NSU researcher must follow the procedures of the entity where the PHI will be obtained. NSU students, faculty and employees have an affirmative duty to request information on research and HIPAA policies from the entity’s Privacy Officer and IRB prior to conducting any type of patient record review or research at an outside entity.

As a general rule, a HIPAA authorization is required for uses and disclosures related to research. Absent a waiver of authorization, human subject research participation at NSU will require that each subject sign a NSU IRB approved research authorization form. The NSU IRB approved research authorization form is a separate stand alone document and should not be combined with, or incorporated into, the informed consent document.

This may be a general statement that the Privacy Rule [HIPAA] may no longer protect health information disclosed to the recipient.

As noted above, in most circumstances a HIPAA authorization is required for uses and disclosures related to research. However, HIPAA Authorization is not required in the following limited circumstances:

- IRB Waiver of HIPAA Authorization- See, HIPAA Research Policy No. 2
- De-identified information- See, HIPAA Research Policy No. 3
- Research on a Decedent’s Information- See, HIPAA Research Policy No. 3
IRB Waiver of HIPAA Authorization:

Due to the passage of HIPAA, there are special situations that apply to research that use Protected Health Information (PHI) without patient authorization. While HIPAA allows for certain waivers or alterations, NSU has taken a more restrictive approach in the interests of fully insuring patient privacy. The IRB will not approve any research that does not follow the normal subject authorization process unless such a waiver is approved by the NSU Privacy Officer and the IRB subsequently specifically approves such a waiver. Except in the case of preparatory research (see following section), such projects will be approved by submission of the standard IRB protocol along with a letter of approval from the NSU Privacy Officer. In cases where research is conducted at another institution, the approval of the Privacy Board and/or privacy officer of that institution must be included in the proposal. Please note that the IRB regards patient privacy and confidentiality as the utmost importance. Therefore, waivers will not be granted frequently. The IRB Center Representatives are available to help and encourage researchers to consider alternative designs which use de-identified data sets, limited dataset agreements, or direct patient authorizations as methods of allowing research with little or no risk to patient confidentiality. The fact that such alternatives are more costly, cumbersome, slower, or inefficient is not a reason to grant a waiver.

De-identified Information:

Information may be used by a researcher or disclosed to a researcher without authorization if the information has been de-identified by an employee of the NSU Health Care Center/Clinic prior to the disclosure. As de-identifying data is considered part of health care operations, a NSU Health Care Center/Clinic is also permitted to provide PHI to a third party to perform this de-identification function pursuant to a Business Associate Agreement. Alternatively, a NSU Health Care Center/Clinic can provide PHI to a non-covered NSU component (i.e., a department that is not a covered component in the NSU hybrid entity designation) to perform the de-identification function.

In order for information to be considered de-identified, all of the following must be removed:

- Names
- Geographic subdivisions smaller than a state (in certain circumstances, the first 3 digits of a zip code can be used)
- All elements of dates (except year) for dates directly related to an individual
- All ages or dates indicating an age over 89 (they can be lumped into one category of 90 or older)
- Telephone numbers
- Fax numbers
- Social security number
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Web universal resource locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

Research on Decedent’s PHI:

HIPAA allows research on the PHI of decedents without authorization from a representative of the decedent; however, such studies must first be approved by the IRB. As part of the research protocol, the researcher must indicate that the study (or an aspect of the study) is to research the PHI of decedents, justify why this is necessary, and the class of individuals to be studied (all deaths, deaths from heart disease, deaths where cause is unknown, deaths in January, etc.) Appropriate means for protecting the privacy of the decedent and relatives (where appropriate) also must be documented. Such review must be approved by the clinical director at each NSU clinic involved.

Reviews Preparatory to Research:

Pursuant to the HIPAA regulations, reviews preparatory to research without patient authorization can be conducted by researchers who are part of the workforce of the particular covered NSU Health Care Center/Clinic that maintains the PHI and by researchers who are not part of the workforce of the particular covered NSU Health Care Center/Clinic\(^1\) that maintains the PHI provided that all of the above-noted requirements are met. However, NSU has implemented the following internal procedures that must be complied with for reviews preparatory to research for each of the following categories:

A. *Researchers Within the Workforce of the Covered NSU Health Care Center/Clinic:*

Reviews preparatory to research involving PHI of a particular NSU covered Health Care Center/Clinic can be conducted by researchers who are part of the workforce of that particular clinic. In such cases, it is the internal procedure of NSU that such researchers are required to receive approval from the applicable NSU covered Health Care Center/Clinic and the IRB prior to commencement of any review preparatory to research.

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\(^1\) NSU is a hybrid entity under the HIPAA regulations. Note that researchers who are not part of the workforce of the particular covered NSU health care clinic may include: (a) individuals who may be workforce members of another NSU health care clinic; (b) individuals who are workforce members of other NSU departments that may not be covered components (e.g., The NSU Office of Clinical Research); and (c) individuals who are not affiliated with NSU.
research. As part of this process, researchers must complete the IRB Review Preparatory to Research Form (Clinic Workforce Version).

B. Researchers Not Within the Workforce of the Particular Covered NSU Health Care Center/Clinic but Who Are Affiliated with another Covered NSU Health Care Center/Clinic or another NSU Department.

Reviews preparatory to research involving PHI of a particular NSU covered Health Care Center/Clinic be conducted by NSU affiliated researchers who are not members of the workforce of that particular clinic. In such cases, it is the internal procedure of NSU that such researchers are required to receive approval from the applicable NSU clinic and the IRB prior to commencement of any review preparatory to research. As part of this process, researchers must complete the IRB Review Preparatory to Research Form (NSU Affiliate- Outside Researcher Version).

C. Non-NSU Affiliated Researchers—“Outside Researchers”

It is the internal policy of NSU that reviews preparatory to research involving PHI of a particular NSU covered Health Care Center/Clinic can only be conducted by outside researchers if the outside researchers receive approval from the applicable NSU clinic and receive a specific waiver of patient authorization from the IRB. As part of this process, outside researchers must complete the IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version).

D. Restriction on Removal of PHI:

With regard to reviews preparatory to research, no PHI may be removed by the researcher from the particular NSU covered Health Care Center/Clinic that maintains the PHI in the course of review. All researchers are required to certify in writing as part of the IRB approval process that they will not remove any PHI from the premises of the NSU covered Health Care Center/Clinic in conducting reviews preparatory to research. It is the policy of NSU that researchers are not permitted to remotely access PHI at the particular covered NSU clinic and they are not permitted to remove any patient identifying information from the premises of the clinic including but not limited to: (a) patient names; (b) patient charts; and (c) any other report, list or document that contains information pertaining to a patient. This prohibition on removal of PHI from the premises applies to all forms of PHI including hardcopy and electronic medium.

E. Reviews Preparatory to Research with Records With Special Protection:

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2 Note that the term outside researchers is used in this section to describe individuals who are not affiliated with any NSU clinic or department.

3 Although the HIPAA regulations do permit a covered entity to allow outside researchers to engage in reviews preparatory to research without patient authorization or without a waiver of authorization granted from the IRB, NSU has implemented an internal policy requiring an IRB waiver of authorization specific to reviews preparatory to research by outside researchers.
Notwithstanding anything to the contrary above, if the review preparatory to research involves: (1) alcohol or substance abuse records governed by 42 CFR Part 2; (2) HIV records subject to Florida Statutes Section 381.004; or (3) mental health records subject to Section 394.4615 of the Florida Public Health Code, special rules will apply and must be complied with as described below.

1. Alcohol or Substance Abuse Records governed by 42 CFR Part 2:

Absent specific written consent from the patient:

PHI may only be disclosed in the context of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

- Is qualified to conduct the research;
- Has a research protocol under which the patient identifying information (i) will be maintained in accordance with the security protocols under the regulations; and (ii) will not be re-disclosed except as permitted under the regulations; and
- Has provided a satisfactory written statement that a group of 3 or more who are independent of the research project has reviewed the protocol and determined that the rights of the patients will be adequately protected and the risks in disclosing the patient identifying information are outweighed by the potential benefits of the research.

A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identifiers.

Any researcher desiring to access PHI for reviews preparatory to research involving records protected under 42 CFR Part 2, must receive approval from the applicable NSU clinic and the IRB prior to commencement of the review preparatory to research. As part of this process, in addition to completing the appropriate form for reviews preparatory to research, researchers must also complete the 42 CFR Part 2 Addendum.

2. HIV Records:

HIV records have special protections under Florida law. Pursuant to Section 381.004 of the Florida Statutes, HIV test results are confidential and cannot be disclosed except in certain circumstances. The statute does provide that disclosures which allow identification of the test subject are permitted to:
Authorized medical or epidemiological researchers who may not further disclose any identifying characteristics or information.

Any researcher desiring to access PHI for reviews preparatory to research involving records containing HIV information must receive approval from the applicable NSU clinic and the IRB prior to commencement of the review preparatory to research. As part of this process, in addition to completing the appropriate form for reviews preparatory to research, researchers must also complete the HIV Records Addendum.


Mental health records are subject to special protections and absent certain exceptions cannot be released without authorization. According to the Florida Public Health Code Section 394.4615 3(b), information can be released:

When the administrator of the facility deems release to a “qualified researcher” is necessary for compilation of treatment data or evaluation of programs.

A qualified researcher is one who after making an application to review confidential data and who, after documenting his or her bona fide academic, scientific or medical credentials and describing the research that gives rise to the request, is determined by the administrator to be eligible to review the data. Notably, personal identifying information obtained by such researcher shall not be further disclosed without the expressed and informed consent of the individual who is the subject of the information.

Any researcher desiring to access PHI for reviews preparatory to research involving mental health records protected under the Florida Public Health code must receive approval from the applicable NSU clinic and the IRB prior to commencement of the review preparatory to research. As part of this process, in addition to completing the appropriate form for reviews preparatory to research, researchers must also complete the Mental Health Records Addendum.

Access to PHI for Research Subjects:

During a clinical study, it may be necessary in some cases to temporarily restrict a patient’s access to certain information within their records. Such restrictions should be as minimal as possible while insuring the validity of the clinical trial. According to 45 CFR 164.524 an individual’s access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may
be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the provider has informed the patient that the right of access will be reinstated upon completion of the research.

FERPA

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

- Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.

- Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth his or her view about the contested information.

- Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):
  - School officials with legitimate educational interest;
  - Other schools to which a student is transferring;
  - Specified officials for audit or evaluation purposes;
  - Appropriate parties in connection with financial aid to a student;
  - Organizations conducting certain studies for or on behalf of the school;
  - Accrediting organizations;
  - To comply with a judicial order or lawfully issued subpoena;
  - Appropriate officials in cases of health and safety emergencies; and
State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student’s name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.

The protection of such records may impact how researchers gain information from student records, solicit subjects, and other elements of a protocol’s methods and procedures. Researchers are encouraged to review information regarding FERPA at the Department of Education’s website http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html).

**PPRA**

The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED) including public schools. PPRA is intended to protect the rights of parents and students in two ways:

- It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis, or evaluation in which their children participate; and
- It seeks to ensure that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:
  1. Political affiliations;
  2. Mental and psychological problems potentially embarrassing to the student and his/her family;
  3. Sex behavior and attitudes;
  4. Illegal, anti-social, self-incriminating and demeaning behavior;
  5. Critical appraisals of other individuals with whom respondents have close family relationships;
  6. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or
7. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

Researchers are encouraged to visit the Department of Education’s website at http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html

*Investigators are reminded that state and local laws may impact their research, in particular the areas of parental consent and child assent, and are required to be familiar with applicable laws prior to conducting research.*
Chapter 5: Research with Special Populations

The federal government has extensively regulated and provided additional safeguards with respect to research, development, and related activities involving "special populations"; which include pregnant women and fetuses, prisoners, and children. The following are guidelines for the inclusion of these special populations as subjects in research. If faculty, staff, and students need additional information and/or clarification regarding special populations, they are to contact the IRB Chair, the Chair's designee, the IRB Administrator, or the Office of Grants and Contracts.

Pregnant Women and Fetuses

No research activities involving pregnant women and fetuses may be undertaken unless appropriate studies on animals and non-pregnant individuals have been completed. The purpose of the activity must be to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity. Individuals engaged in the research activity will have no part in 1) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and 2) determining the viability of the fetus at the termination of the pregnancy; and 3) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

1. Pregnant Women as Subjects

No pregnant woman may be involved as a subject in any research activity unless the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus is minimal. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus. The father's informed consent need not be secured if his purpose of the activity is to meet the health needs of the mother; his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.

2. Fetuses in Utero as Subjects

No fetus in utero may be involved as a subject in any research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent. The father's informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.
3. Fetuses ex utero, Including Nonviable Fetuses, as Subjects

Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in any research activity unless there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability. No nonviable fetus may be involved as a subject in any research activity unless vital functions of the fetus will not be artificially maintained; experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed; and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements included herein. Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father’s informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape. Activities involving a dead fetus, macerated fecal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities.

Prisoners

Inasmuch as prisoners may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, additional safeguards for their protection must be adhered to. With respect to research involving prisoners, the IRB shall also meet the following specific requirements:

- A majority of the Board (exclusive of prison members) shall have no association with the prison(s) involved, apart from their membership on the Board
- At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB Board, only one Board need satisfy this requirement.

The following research involving prisoners is permitted:

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:
1. the institution has certified to DHHS that the IRB has approved the research, and in the judgment of the agency, the research involves solely the following:
   - the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
   - the study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
   - research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere);
   - research on social and psychological problems (such as alcoholism, drug addiction, and sexual assaults) only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his or her intent to approve such research; or research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject.

In cases in which studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the research may proceed only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his/her intent to approve such research.

It is important to reiterate that investigators cannot use prisoners as a sample of convenience and that any study involving prisoners will be reviewed carefully for coerciveness and to be sure that study risks inherent to this population have been minimized.

**Children and Wards**

Information related to the IRB’s policy on research with children and wards may be found here:

**Workers/Employees**

Research conducted on workers or employees should take into consideration the potential status of these individuals as vulnerable subjects. Concerns such as coercion (particularly when the investigator is also an employer or supervisor), confidentiality, privacy, and permission by an employer to work with his/her employees must be evaluated and minimized.

**Students**

The relationship of teacher and student is one that automatically questions the voluntary nature of a student’s participation. Instructors who are researchers must be sensitive to
potential coercion and must design protocols in consideration of this fact. The IRB does permit giving extra credit/credit to students who participate in research only when alternative means of obtaining credit are available to students who do not wish to volunteer for research. The extra credit/credit must be calculated and announced to the class, preferably within the syllabus, in advance. Additionally, the non-research extra credit activities must be comparable in time/commitment as the research activities. The Board will likely consider non-research activities that are not comparable to the proposed research activities as coercive. In order to maintain the voluntary nature of participation in research, students should also be able to elect to leave the research activity at any time and complete one of the other non-research extra credit activities to be able to still earn the credit. Protocols should be designed so that subject recruitment is not conducted by the instructor/researcher. Instead, a colleague should be called upon to explain the study and solicit students, and then allow for adequate time for the students to decide if they would like to participate in the research. Beyond this, informed consent procedures for students should adhere to NSU guidelines and the Common Rule in all aspects.
Appendix A
NSU-IRB New Protocol Form
Nova Southeastern University
Institutional Review Board for Research with Human Subjects (IRB)
New Protocol Submission

Center Rep: | To be completed by IRB Office
---|---
Date Sent to IRB: | Protocol Number:

**Instructions:** In order to comply with federal regulations and with the university's IRB guidelines, the Principal Investigator (PI) is required to complete all of the following items. After completing, submit this document and all consent forms and research instruments (questionnaires, interviews, etc.) to the appropriate IRB College/Center Representative. You can find your college/center representatives using the following link: [http://www.nova.edu/irb/membership.html](http://www.nova.edu/irb/membership.html).

- If your study qualifies for center level exemption from further review, the Center Representative will exempt your study, provide you with a memo to that regard, and give you copies of the stamped, approved consent/assent form(s), if applicable. The Center Representative will log your study into the IRB database and forward a copy of the complete submission to the IRB office.
- If your study appears to qualify for expedited review, then once the Center Representative believes the submission is complete, the Center Representative will log your study into the IRB database and forward ONE complete submission packet to the IRB office for review.
- If full review is required, the Center Representative will log the study into the IRB database and will provide the PI with instructions for submitting 23 stapled or rubber banded copies (AND 1 unstapled original) of the submission and all supporting materials (research protocol, consent/assent forms, letters of authorization, etc.) to IRB. Please note: ONLY ONE copy of all research instruments (tests instruments, interview protocols, etc.) needs to be submitted. The completed package must be received by the IRB by the last business day of the month prior to the next scheduled IRB meeting. Because mail, including express delivery, takes at least a day to be delivered within the university, please make allowance for this in your planning. Incomplete submissions will delay review by the IRB. The IRB reserves the right to postpone review of protocols at convened meetings due to needed revisions.

**Use a word processor to complete this form.** You do not need to be concerned about where page breaks fall. You are to complete all **BLUE** sections. Be sure that all pages, including any appendices or attachments, except for consent/assent forms and advertisements, are numbered sequentially. For further information, refer to [http://www.nova.edu/irb/manual/policies.html](http://www.nova.edu/irb/manual/policies.html) and [http://www.nova.edu/irb/process.html](http://www.nova.edu/irb/process.html).

Do **not** approach subjects about being in the research study until you have received NSU IRB approval.

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1. General Information

1.A. Research Project Title:

1.B. Insert Principal Investigator’s (PI) Last Name and Date of Submission in the footer.

1.C. Brief Overview (Max 250 Words):
### 1.D. Principal Investigator (PI) Information

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<td>Daytime Phone</td>
<td>Faculty</td>
</tr>
<tr>
<td>Alternate Phone</td>
<td>Staff</td>
</tr>
<tr>
<td>NSU Email Address</td>
<td>NSU Center/College/Dept</td>
</tr>
<tr>
<td>Alternate Email Address</td>
<td></td>
</tr>
<tr>
<td>Degree/Academic Information</td>
<td>PI CITI Completion Date*</td>
</tr>
</tbody>
</table>

Please briefly describe your applicable professional, educational, employment, professional licensure, and research experience. Do **NOT** attach your vitae.

### 1.E. Co-Investigators (Co-I) Information (including faculty advisers)

<table>
<thead>
<tr>
<th>Co-Investigator 1</th>
<th>Co-Investigator 2</th>
<th>Co-Investigator 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mailing Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Phone Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree/Academic Information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CITI Completion Date*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please briefly describe applicable professional, educational, employment, professional licensure, and/or research experience for all co-investigators. Do **NOT** attach vitae.

### 1.F. Research Assistant Information (if applicable)

<table>
<thead>
<tr>
<th>Research Assistant 1</th>
<th>Research Assistant 2</th>
<th>Research Assistant 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mailing Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CITI Completion Date*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NOTE: CITI must have been completed within the last 3 years. If a member of the research team is affiliated with another institution, please include a copy of that individual’s training certification.

### 1.G. Funding Information

<table>
<thead>
<tr>
<th>Funding status</th>
<th>Unfunded</th>
<th>Funding Applied For</th>
<th>Funded</th>
</tr>
</thead>
</table>

**If you indicated “Funded” or “Funding Applied For,” complete the following.**

<table>
<thead>
<tr>
<th>Source of Funding</th>
<th>Grant</th>
<th>Subcontract</th>
<th>Contract</th>
<th>Fellowship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title (if different from above)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principal Investigator (if different from above)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of Application</td>
<td>Grant</td>
<td>Subcontract</td>
<td>Contract</td>
<td>Fellowship</td>
</tr>
<tr>
<td>Award Amount:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 1.H. Management of Conflict of Interest

I certify that I, as PI, have read these guidelines, and have verified that my co-investigators and research assistants also have read these guidelines.  

PI Initials

Do any investigators have a significant financial interest (as defined by NSU policy) in relation to this study?  

Yes  

No

If yes, please describe the nature of the conflict of interest below

If you answered yes, please be sure to include the following statement, or a similar statement, within the description section of the consent forms: “The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study.”  

Continue, describing the conflict in the consent/assent documents.

### 1.I. Dates and Phases of Study

<table>
<thead>
<tr>
<th>Proposed Start Date</th>
<th>Shortly after IRB approval</th>
<th>Other (list date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed Duration of Research (including analysis of the results)</td>
<td>One year or less</td>
<td>Other (describe, please note minimum annual continuing review required)</td>
</tr>
</tbody>
</table>

Is this a multi-part study?  

Yes  

No

If “Yes,” please note that procedures used in later phases may affect the review status of this study. Briefly describe the later stages.
### 1.J. Multiple Site Information

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will the study be conducted at an NSU location?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If “Yes,” provide the location within NSU, e.g. department or clinic.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will the study be conducted at a non-NSU location?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will any of the activities be done online or via telephone (e.g., completion of surveys, delivery of instructional content)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If “Yes,” for the Internet based activities, will these be done via a secure site?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If “Yes,” please complete the following for the non-NSU sites. Include these sites on the consent form in the “site information” section.

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Address</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

You will need documentation of permission to conduct the research at non-NSU sites. Attach the permission letter(s) or IRB approvals to this document.

### 1.K. Cooperative Research

Cooperative research projects are those that involve more than one institution or when an investigator is employed at or is an agent of an institution other than NSU, (For more information, see [http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html](http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html)). Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations.

<table>
<thead>
<tr>
<th>Does this research involve cooperative research?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Has this proposal been submitted or will the proposal be submitted to another Institutional Review Board (or authorizing individual, entity, or ethics review board) for review?

<table>
<thead>
<tr>
<th>If “Yes,” please complete for each site. Please attach documentation of approval. (Copy the section of the table and add if there are multiple sites.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Institution</td>
</tr>
<tr>
<td>IRB/Administrative Decision (check applicable)</td>
</tr>
<tr>
<td>Approved</td>
</tr>
<tr>
<td>NSU IRB approval required prior to submission</td>
</tr>
<tr>
<td>Submitted (not yet approved)</td>
</tr>
<tr>
<td>Not yet submitted</td>
</tr>
</tbody>
</table>
2. Subject/Participant Information

2.A. Overview of Proposed Subjects/Participants
(complete all that apply and provide maximum number proposed within each category):

<table>
<thead>
<tr>
<th>Subject Group</th>
<th>Fetus in Utero/ non-viable fetuses/ abortuses</th>
<th>Newborns or Infants</th>
<th>Children (aged 2-6)</th>
<th>Children (age 7-12)</th>
<th>Adolescents (aged 13-17)</th>
<th>Adults (18+)</th>
<th>Pregnant Women</th>
<th>Adults with Guardians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark X for each proposed subject type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of Proposed Subjects*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please briefly describe your potential subjects:

*By proposed subjects, the IRB means subjects who will consent to be in the study and begin the study activities.

2.B. Subject Vulnerability

Do any subjects have limited decision-making autonomy, have communication problems that would limit ability to dissent to study procedures, belong to a group that is vulnerable to coercion, or belong to a group defined by regulation as requiring greater care?

If you indicated "Yes", please mark with an X next to each applicable category in the column to the right and complete the remainder of this section

Prisoners
Pregnant Women
Cognitive impairment or emotional problems that potentially limit decision making
Communication impairments that may preclude communicating a decision to discontinue participation or refuse participation
Students of the investigator or investigator’s department
Employees of the investigator or investigator’s department
Children (minors)
Terminally ill
Other (specify):

If you indicated any of the above, please justify your rationale for including these subjects.

If you are using potentially vulnerable subjects as described above (infants, children, pregnant women/fetuses, terminally ill, decision-impaired, communication-impaired, students/employees, or prisoners), does the research create greater than minimal
If your subjects have a vulnerability that arises from their being students in your class or department, you will be asked for more information in Section III.G. If the subjects have one of the other vulnerabilities, please describe proposed safeguards to protect vulnerable subjects.

If not evident from the researcher qualification information in I.D. or I.E., please describe the researcher(s) qualifications for working with vulnerable subjects.

### 2.C. Study Design and Methodology

#### Part 1 – Purpose

Please briefly describe the **purpose** of your study. Note: Examples of study purposes are “to determine if a new reading intervention program improves 4th graders’ reading scores” or “to survey patients on their perception of physical therapy services”.

#### Part 2 – Goals and Justification

Briefly elaborate on the main **goals and justification** for the study. Summarize the background, rationale, nature, and significance of the proposed research. Include a brief overview of your prior research in the area, or literature that supports the need for this study. This section should be a brief overview, and typically is not more than a few paragraphs in length. You will be asked about procedures and instruments later in the submission.

#### Part 3 – Steps in the Research Study

In the box below, please outline in detail the **steps in the research study** in order as they will occur after consent has been secured. If there are different requirements for different groups/types of subjects within the study, please separate out the steps per group. Indicate how long the subject spends completing the different steps/procedures. Be specific about the tests given and/or treatments used, when they will occur, and their frequency.

#### Part 4 – Sources of Data Information
Are you using questionnaires, tests, instruments, or forms?  
If “Yes”, list them below and include a copy of each as appendices.

---

Do you plan to use any data from records or archives?  
If “Yes”, please describe (such as data originally created for non research purposes or data created as a result of a previous study).

---

Do you plan to use any de-identified data?  
If “Yes”, please describe the data and how it will be de-identified.

---

3. Additional Study Information

3.A. Clinical Testing

Food and Drug Administration
Investigational Drugs and Devices

Does the study involve the use of an investigational drug?  
If “Yes”, has an Investigational New Drug application been submitted for the drug?

---

Does the study involve the use of an investigational device?  
If “Yes”, has an Investigational Device Exemption (IDE) been, or will be, secured prior to the start of the study?

---

Does the study use any device (either as a part of the experiment or to collect data) that has not received FDA approved for clinical/medical use or is being used in a manner not consistent with its cleared/marketing status?  
If “Yes”, please describe the device and how its use differs from its approved status by the FDA.

---

Clinical Procedures
Does the study involve the use of any procedure that is not used in routine clinical practice?  

Yes [ ]  No [ ]

If “Yes”, please list the procedures.

---

3.B. Sensitive Information

Are you asking questions about sensitive issues, such as illegal activity, sexual history, or anything else that, if made public, could jeopardize a person’s reputation, employability, safety, or quality of life?  

Yes [ ]  No [ ]

If “Yes”, please describe the information.

---

Does the study involve the collection of data from voice, video, digital, or image recordings made for research purposes?  

Yes [ ]  No [ ]

If “Yes”, please describe the procedures associated with these recordings.

---

3.C. Non-English Speaking Participants

Will the study involve non-English speaking participants?  

Yes [ ]  No [ ]

Will the study require translation of consent forms?  

Yes [ ]  No [ ]

If you answered “Yes,” please specify the language(s) that the consent forms will be translated in to:

---

If you are including non-English speaking participants, when you complete section III.H., please discuss how you will ensure that the participants understand the study, including the use of a qualified translator to provide oral consent information.

---

3.D. Subject Compensation

Will your subjects receive any payments, incentives, or gifts?  

Yes [ ]  No [ ]

If “Yes,” please indicate the types of compensation. Otherwise move on to section E.

- Monetary Payment [ ]  Gift [ ]  Extra credit (Students) or Workplace Incentive (Employees) [ ]
### Other incentive

Please describe:

Describe the payment(s)/gift(s)/incentive(s), and if it is a gift, estimate its monetary value. Indicate whether all participants are given the payment/gift/incentive, or if only some are eligible. (Note: the value of the payment/gift/incentive should not be so significant that it might compromise the subject’s good judgment.)

Describe when the subject will receive the payment/gift/incentive, and whether the amount differs depending upon whether different portions of the study are completed or is limited if the subject discontinues participation during the study.

### 3.E. Inclusion / Exclusion Criteria for Subjects

Describe the inclusion and exclusion criteria for the proposed subjects. Please list the criteria in bullet or outline format rather than narrative. If the study limits participation based on gender, age or race, please justify the exclusion criteria. (Subject protection and appropriate study design may require specific inclusion or exclusion criteria, but the IRB does not permit subject selection that is not equitable or prevents a subpopulation from benefiting from the scientific discoveries of the study.)

**Inclusion Criteria**

**Exclusion Criteria**

### 3.F. Subject Recruitment

How will you recruit subjects (approach/invite/or ask people to be in your study)?

**Recruitment Advertisements, Fliers, and Letters**

Are you using any letters, fliers, or advertisements?  

Yes  No

If you answered yes, please list the type(s) below and attach a copy of the proposed materials as an appendix (do not copy and paste the flyer into this form). (Note: Materials should list “Nova Southeastern University”.)
### 3.G. Potential for Coercion in Subject Recruitment

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are any of the subjects a student or advisee of the PI or a Co-I?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PI or a Co-I serve in any capacity (e.g., administrative, therapeutic) that might affect a subject’s willingness to participate?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

If “Yes” to either of the above, then describe the relationship of the subjects and investigator.

If you answered yes, please read the NSU policy about use of students in research. [http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf](http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are any of the subjects employees of, or report to, the PI or a Co-I?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are any of the subjects a patient of the PI or a Co-I?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are any of the subjects a patient within a PI or a Co-I’s clinical practice?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Are any of the subjects informed about the study by their doctor / clinician?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

If you answered “yes” to any of the questions in this section (3.G.), please describe how you will ensure that the subjects will feel free to decline participation without fear of reprisal. If the subjects are patients, how will you prevent “therapeutic misconception” (the mistaken belief that when a care provider provides information about a study, it means that the provider thinks that study participation will benefit the patient).

If you are providing any incentive to the student/employee subjects, discuss whether there is a mechanism for students / employees to receive the incentive by doing something other than participating in the research project (see [http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf](http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf)).

### 3.H. Informed Consent

**Part 1 – Consent Process**
Informed consent is a process that begins with advertising or telling potential subjects about your study, continues as the investigator or staff provides details to potential subjects via dialog, and is formalized by the signing of the consent.

Note: Minors must have consent of their parents or guardians before you can approach the minor about participating in the study.

Note: Allow as much time as possible and feasible for the subject to think about whether to enroll in the study. Generally, the greater the study risks, the longer the decision period.

Please overview the steps in the consent process in your research study. If there is more than one group of subjects, separately describe the process for each group.

Part 2 – Consent Process and Document Waiver/Alteration Information

In most cases, subjects need to participate in a meaningful consent process and receive a consent/assent form that documents agreement to participate in research. However, in a few cases the subject’s confidentiality is protected by waiving/altering consent procedures or the requirement for signed consent forms. Please read the IRB’s policy on informed consent for explanations, including what the IRB must demonstrate to permit waiver or alteration (http://www.nova.edu/irb/manual/forms/informed_consent.pdf). Please note, however, that while your study may qualify for waiver or alteration, that determination is at the discretion of the IRB.

One case where a signed informed consent form is NOT used is when a researcher is only reviewing existing/archival data that were collected for non-research purposes. If the data are obtained from the records by someone with authorization, and the data are de-identified, then it may be appropriate not to ask subjects (those whose data you are collecting) to provide consent, because the research involves no more than minimal risk, the waiver or alteration will not adversely affect the rights or welfare of subjects, the research could not practicably be carried out without the waiver or alteration, and, when appropriate, the subject will be provided pertinent information about participation. (NOTE: If your study has other procedures that require interaction with subjects or prospective collection of data, it is unlikely that waiver or alteration of consent procedures or the signing of consent forms would be appropriate.) If this describes your study, then you may request a waiver of the requirement for informed consent and the documentation of signed consent.

If you think this applies in your study, please describe your rationale.

Another situation involving waiver or alteration of the requirement to obtain a signed consent form is when the research only entails conducting anonymous surveys that are not intrusive. If there is no way that the subjects’ responses could be linked to them, then waiving the requirement for a signed consent form would minimize a risk to their confidentiality and privacy because the only record linking the subject and the research would be the consent form. If the principal risk would be
potential harm resulting from a breach of confidentiality and the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context, then the elements of informed consent are put into the survey itself. The person indicates his/her voluntary participation by completing the survey after being advised about the study and voluntary nature of his/her participation.

If you think this applies in your study, please describe your rationale.

<table>
<thead>
<tr>
<th>If you think this applies in your study, please describe your rationale.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

There may be other cases where you would wish to ask for a waiver or alteration of informed consent or signed consent documentation.

If you are seeking a waiver or alteration, please describe your rationale.

<table>
<thead>
<tr>
<th>There may be other cases where you would wish to ask for a waiver or alteration of informed consent or signed consent documentation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you are seeking a waiver or alteration, please describe your rationale.</td>
</tr>
</tbody>
</table>

### Part 3 – Consent and Assent Document Information

Typically, you are asked to use the NSU format consent and assent forms. However, if this is cooperative research, or sponsored research that requires the use of a different template or model, you may use their format.

- [ ] I will use NSU format consent/assent forms
- [ ] I will be using another institution’s format for consent/assent forms (NOTE: Please review the other institution’s consent forms and the NSU requirements to be sure that all of the NSU requirements are present. You may also want to discuss the consent forms with your college/center representative)
- [ ] As noted above, I am requesting a waiver/alteration of consent and/or signed consent form requirements
- [ ] If you have different procedures for different groups of subjects, you will need a separate consent and/or assent form for each group. If the reading level of different groups of subjects differs, this may also require you to have different consent and/or assent forms (e.g. young children vs adolescents). If your subjects are children, you will also need parental consent.
  - [ ] What is the total number of consent/assent form types that you plan to use?
  - [ ] If using more than one consent form, create a list below that describes the different forms that you will be using (e.g. 1. Teacher consent form, 2. Parent consent form, 3. Assent form for children age 7-12, 4. Assent form for adolescents).

Include copies of the consent / assent forms. When you attach the consent forms, put them in this order. Please note that the IRB prefers that the consent document be written using the simplest language possible, and strongly recommends the question and answer format (see [Document Model #1 for Adult/General Consent Form](#) [Readability Score: Grade 6]).
### 3.I. Protected Health Information Use

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you obtaining any data from the subject’s medical record?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you asking the subject about his or her health information, and doing so in a clinic or entity that would normally be subject to HIPAA regulations on protected health information?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If you answered “Yes” to either question, continue. Otherwise go on to section 3.J.**

Please review the NSU HIPAA research policies available at [http://www.nova.edu/irb/manual/policies.html](http://www.nova.edu/irb/manual/policies.html) for more information.

Please note that effective 12/10/2009 the NSU IRB no longer reviews separate HIPAA authorizations for research. It is the principal investigator’s responsibility to use the correct HIPAA authorization as outlined in the aforementioned policy. In instances where the HIPAA authorization must be a part of the informed consent form for research, the NSU IRB will review the compound consent.

Specify the exact data to be gathered (e.g., weight, blood pressure, IQ score, diagnosis, depression rating, number of treatments, etc.).

### Which procedure are you proposing to use? (Check)

- I will obtain the subject’s authorization to obtain the protected health information via the NSU Authorization for Use and Disclosure of Protected Health Information in Research (research activities will be occurring at an NSU clinic).
- I will obtain the subject’s authorization to obtain the protected health information via the authorization for use and disclosure of protected health information in research provided by the non-NSU covered entity.
- The protected health information data are a fully de-identified data set (data obtained without recording any patient information, with the data accessed by an employee of the institution).
- The data are part of a limited data set agreement as defined by the Office of Human Research Protections. (Attach a copy of the agreement.)
- If part of a limited data set agreement, what is the justification that confidentiality is protected?
- I have a waiver provided by a duly constituted privacy board. (Attach a copy of the waiver.)

### HIPAA Research Authorization

If the research is to be conducted at an NSU clinic, have you created a HIPAA authorization form as outlined in the HIPAA Research Policy No. 1 ([http://www.nova.edu/irb/manual/policies.html](http://www.nova.edu/irb/manual/policies.html)) and in keeping with the Instructions for Preparing the Authorization For Use and Disclosure of Protected Health Information in Research Form and the model form provided ([http://www.nova.edu/irb/manual/forms.html](http://www.nova.edu/irb/manual/forms.html))?

Please note, do NOT submit a copy of the HIPAA authorization form if you are following the model noted in the aforementioned policy.
If the research is to be conducted at a non-NSU covered entity, have you reviewed the HIPAA Research Policy No. 6: Guidance on Research at Outside Entities ([http://www.nova.edu/irb/manual/policies.html](http://www.nova.edu/irb/manual/policies.html))?  

Researchers are advised to discuss the proposed research with the applicable HIPAA privacy officer at the non-NSU covered entity.

Does the researcher sponsor or cooperating agency require the incorporation of the HIPAA authorization within the consent document (Compound Consent)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If yes, please briefly indicate who requires that this be in the informed consent document.

Please note, consent forms that include the HIPAA authorization may need approval from the university Office of Corporate Compliance.

### 3.J. Student/Academic Information Use

Are you obtaining any data from the subject’s academic records?  

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**If you answered “Yes”, continue. Otherwise go on to section K.**

Specify the exact data to be gathered (e.g., GPA, standardized test score, IQ score, medical/psychological information stored in academic files, attendance records, disciplinary records, etc.).

Specify how you will obtain the data.

**Which procedure are you proposing to use? (Check all that apply)**

- I will obtain the subject’s consent to obtain the academic information.

- The academic information will be a part of a fully de-identified data set (data obtained without recording any subject information, and provided to you in keeping with the institution’s policies and the Federal Educational Rights and Privacy Act [FERPA]).

### 3.K. Risks, Discomforts, & Inconveniences

In this section, discuss all potential risks (physical, economic/financial, legal, psychological, social, etc.), discomforts, or inconveniences to the subjects.

- All studies using identifiable subject information must address the issue of possible loss of subject confidentiality
- Some possible risks include physical, psychological or emotional harm, breach of
confidentiality, and invasion of privacy.
- Discomfort includes anticipated risk for mild physical or emotional pain.
- Study inconveniences include loss of time or pay.

Each risk, discomfort and inconvenience should be addressed individually in the following format (use the tables provided and copy if the study presents more than 3).
- List each item individually
- Discuss likelihood: How likely is it that this risk/discomfort or inconvenience will occur? This is usually classified as minimal, moderate, or high.
- Discuss magnitude/duration: How dire is the risk/inconvenience/discomfort, and if it occurs, how long do you expect that the subject will be affected?
- Discuss risk minimization: Describe the procedures undertaken to minimize the risk that this specific risk/discomfort/inconvenience will occur.

<table>
<thead>
<tr>
<th>Risk/Discomfort</th>
<th>Likelihood</th>
<th>Magnitude/Duration</th>
<th>Risk Minimization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk/Discomfort</td>
<td>Likelihood</td>
<td>Magnitude/Duration</td>
<td>Risk Minimization</td>
</tr>
<tr>
<td>Risk/Discomfort</td>
<td>Likelihood</td>
<td>Magnitude/Duration</td>
<td>Risk Minimization</td>
</tr>
</tbody>
</table>

One way in which confidentiality is partially protected is to destroy study documents containing identifiable information when they are no longer needed. The IRB requires that study materials be kept for a minimum of three years from the end of the study to permit study auditing; you may elect to keep them for a longer period of time and study sponsors may have their own data retention requirements. Please indicate when and how you plan to destroy data that contains identifiable subject information, such as consent forms, lists that link subject identity to data coding, or raw data containing subject names.

3.L. Benefits to Subjects
In this section, discuss all direct benefits of the study to participants. This does not include “helping research” or other generalities, nor does it include compensation for participation. Some examples of benefits include receiving free treatment, receiving a list of reputable local services, or obtaining tutoring. The value of any such benefits should be listed as well. If there are no direct benefits to the participants, this should be indicated.

Are there any direct benefits to the research participants?

<table>
<thead>
<tr>
<th>Option</th>
<th>Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no direct benefits to study participants</td>
<td></td>
</tr>
<tr>
<td>This study provides benefit to, or is likely to benefit, the participants</td>
<td></td>
</tr>
</tbody>
</table>

List/describe each benefit

3.M. Data Analysis Plan
Please describe preliminarily proposed data analysis procedures.

3.N. Scientific Benefit
Briefly discuss how generalization of the information obtained from this study will be scientifically useful, or useful to your research site.

3.O. Risk/Benefit Ratio
To be approved, a study needs to have greater benefits than risks. Why do you believe this study has a positive benefits-to-risks ratio?

3.P. Safety Monitoring Plans
All researchers are required to report adverse events and unanticipated problems in keeping with the NSU IRB policy (http://www.nova.edu/irb/manual/forms/adverse_events.pdf).

Studies that entail significant risk to subjects, such as randomized controlled drug trials, may warrant safety monitoring by an outside safety board. Does your study utilize a Data Safety Monitoring plan?

If "Yes," please describe the safety monitoring plans. Please specify if the study will be monitored by the investigators, sponsors (if applicable), or a Data Safety Monitoring Board (DSMB).

Sponsored studies may reference an attached Investigator Brochure.

3.Q. Other Information

If there is other information about this study that is required in order for those reviewing the study to fully understand the study, its risks and benefits, please describe below.
### 3.R. Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including any supporting documents) is a complete and accurate description of the proposed study. I agree to the following:

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>This study will be conducted in the manner described in this submission and will not be implemented (including subject recruitment or consenting) until all applicable IRBs have granted permission to conduct the research. No changes to this study will be implemented until an amendment form has been submitted and approved by the IRB.</td>
<td>PI Initials</td>
</tr>
<tr>
<td>If the IRB approves this study via expedited or full procedure, I will submit for continuing review as stipulated in the approval letter. If the study or data analysis will exceed the approval period, I will submit a Submission Form for Continuing Review of IRB Approved Studies in a timely manner (well in advance of the renewal date). I understand that study activities may not continue past an approval period.</td>
<td>PI Initials</td>
</tr>
<tr>
<td>I will provide a copy of the signed consent form to the subject or patient, if applicable.</td>
<td>PI Initials</td>
</tr>
<tr>
<td>I will retain all signed informed consent documents and study-related records for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date the study is concluded.</td>
<td>PI Initials</td>
</tr>
<tr>
<td>I will report in writing any serious adverse events to the IRB within 24 hours and all other adverse events and unanticipated problems within 5 working days.</td>
<td>PI Initials</td>
</tr>
<tr>
<td>I will provide participants with any significant new information obtained during the course of the study and submit reports of new information to the IRB as a Study Amendment.</td>
<td>PI Initials</td>
</tr>
<tr>
<td>If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed (no further data collection or analysis). This report will be provided no later than 30 days after the end of the study via the IRB Closing Report Form.</td>
<td>PI Initials</td>
</tr>
</tbody>
</table>

Principal Investigator's Signature: ___________________________ Date: ____________________

### 3.S. Co-Investigator Assurance and Obligations (for Student PIs)

If this study is for the completion of a degree requirement, the thesis adviser or dissertation chair must sign the attestation below.

- All departmental approvals by the student’s committee (if applicable) and chair or thesis adviser have been completed.
- I accept that the University and IRB consider the faculty advisor’s responsibility to be equal to that of the student in regard to
  - The quality of the research design AND the accuracy of the protocol
  - The appropriateness of the recruitment methods, the design of the process for informing the subjects about the nature of the study, and the process of obtaining informed consent
  - The readability, accuracy, and format of the informed consent/assent document(s) and the explanation of all informed consent procedures.

My signature below attests that I have read this submission in its entirety and believe that it is accurate, complete, appropriate, and adheres to the principles of the Belmont report and that all departmental approvals by the student’s committee have been completed.

Chair/Adviser’s Signature: ___________________________ Date: ____________________
Appendix B
Informed Consent Form Instructions
Frequently Asked Questions Regarding Informed Consent
Exceptions from Requirements for Informed Consent
Informed Consent Form Checklist
Consent Form Instructions
Version: 12/10/2009

General Considerations

One significant outcome of the Nuremberg medical trials was the establishment in 1947 of the Nuremberg Code, which set forth ten principles for conducting research involving human subjects. The first of those principles states, "the voluntary consent of the human subject is absolutely essential." Thus, no investigator may involve a human being as a subject in research, as defined in this policy and procedure manual, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e. his or her consent is voluntary. Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this manual.

Additionally, the researcher should be aware that litigation against the University is always a possibility. From this perspective, even an ethical informed consent is not sufficient. Rather, we need an ethical informed consent which is legally valid and the legal validity of which can be demonstrated should such a need arise.

Researchers are to use consent forms that have been stamped by either the center representative or the IRB as permitted.

The researcher should also be aware that signed informed consent form documents must be retained for a minimum of three (3) years from the date the study is concluded (or longer depending on the requirements of certain funding agencies).

Types of Informed Consent Forms

There are four types of consent forms. Please note that the IRB has provided two different templates for the Adult/General Consent Form and for the Parental Consent Form (these instructions are applicable to both templates):

Adult/General Consent Form

Used for subjects 18 years and over who are capable of giving informed consent. This includes most adult subjects. In some cases, parents are participating in a study while their child is not. The Adult/General Consent Form would be the appropriate choice. If parents are giving consent for both their child to participate in a study and agreeing to participate themselves at the same time, the Parent/Guardian Consent Form should be used.

Consent Forms should be written at a readability level commensurate with the
proposed subjects. It is recommended that consent forms not exceed the 8th grade reading level in most cases.

Child Assent Form

For children between the ages of age 7 and 12, an assent form is used which is written in a simpler format with language appropriate to the youngest child in this age range; however, it still contains the major required elements. This form is used in conjunction with the Parent/Guardian Consent Form. For children under 7, the same information needs to be conveyed but may be done orally at the child’s level of development. The oral explanation of the study to the child should be attested to by the parent on the Parent Consent Form when a written assent is not possible. Infants and children unable to understand do not need a written assent.

You will note that the IRB has provided model assents at two different readability levels. Researchers are encouraged to consider the population of their study as they develop their assent forms. These model forms are suggestions. Researchers are also encouraged to use readability tools available in many word-processing software such as MSWord. See Readability Tool instructions on the following IRB Web site (http://www.nova.edu/irb/manual/forms.html). Remember that the consent forms should be written for the readability level of the youngest participant and/or the lowest grade/readability level.

Adolescent Assent Form

Used when subjects are in the age range of 13-17. The Adolescent Assent Form is generally the same as for the adults except it is written in language appropriate to the youngest teenager to be included in the study. This form is used in conjunction with the Parent/Guardian Consent Form.

You will note that the IRB has provided model assents at two different readability levels. Researchers are encouraged to consider the population of their study as they develop their assent forms. These model forms are suggestions. Researchers are also encouraged to use readability tools available in many word-processing software such as MSWord. See Readability Tool instructions on the following IRB Web site (http://www.nova.edu/irb/manual/forms.html). Remember that the consent forms should be written for the readability level of the youngest participant and/or the lowest grade/readability level.

Parent or Guardian Consent Form

Anytime a subject under 18 is used consent must be obtained from the parent or guardian. This form is again similar to the Adult/General Form. However, rather than saying “you” the subject is referred to as “your child.” This form would also contain information regarding any parental/guardian participation in the study. If the study requires a guardian of an adult to provide consent it should read “your ward.”
Consent Forms should be written at a readability level commensurate with the proposed subjects. It is recommended that consent forms not exceed the 8th grade reading level in most cases.

Studies may need to use only one or several of these forms, depending on the groups involved in the research. For example, if different procedures are used for teachers and parents, use two different consent forms.

**General Requirements for the Consent Form**

All sections described below must be included in every consent form. The length or applicability to a given study may vary, but the sections must appear in the standard order listed on the example document layouts. This allows the IRB to see quickly that the researcher has considered all elements of the consent form.

- The first page of the consent form should be on Nova Southeastern University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable. All letterhead must be the original, not a copy and not digitally created. All proposed consent forms must be submitted on NSU letterhead as well. Please contact your Center Representative for NSU letterhead.

- The consent form should be in language understandable to the subject or his or her legal representative. It must be written in a consistent voice: either first, second, or third person (not a combination). In general, the consent form should be in second person (“You are being asked to participate….“). The consent language of the child or adolescent assent should account for the ages of the subjects. For subjects who would better comprehend the consent form in their native language the consent must be provided in a translated version.
Translations and Translation Services

For protocols that may be reviewed at the Center Level or Expedited Review Level the IRB will permit researchers to translate consent materials and instruments themselves and submit the original English and Spanish versions for review by the designee of the IRB chair. Such translations should not be submitted until the English version of consent materials is approved. The translation does not have to be conducted by a certified translator. For documents translated into all other languages, the IRB requires that the documents be translated by a certified translator unless the Chair can identify a member of the IRB or an appropriately trained individual who is able to check the translation. Please contact your center representative or the IRB office regarding other languages.

For protocols requiring a full review, all documents that are to be translated must be translated by a certified translator unless this is waived by the Full IRB.

The university recommends but does not mandate that researchers use the services of Student Services International, Inc. for the certified translations.

Student Services International, Inc
2455 East Sunrise Boulevard, Suite 200
Fort Lauderdale, FL 33304
954-565-8505 xt 29
fax 954-565-8718
www.talkinusa.com

Regardless of the translation service, documentation must be provided that states the translator is certified.

Translations should not be commenced until the IRB has approved the English version of the consent materials and instruments.

If the research is externally funded, the funding agency should be listed under funding source.

The title of the study and the name, address, and telephone number of the investigator(s) follow immediately after funding source. The Principal Investigator's address and phone number, and the number of the IRB Office (954-262-5369) must appear on the consent form. If the principal investigator is a student, the address and phone number of his/her advisor(s)/clinical supervisor(s) must also appear on the form. If the research is conducted as a setting where contacting the researcher or the advisor might be difficult (such as when the research is done out of state or in a prison) a local contact who the subject can easily reach should also be listed.
• Informed consent should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.

• Language that states that research files could be audited by regulatory agencies when appropriate.

• When required by the IRB, one or more of the following elements shall be provided to each subject:
  (a) Statement that procedure may involve unforeseeable risks to the subject;
  (b) Description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent;
  (c) Additional costs to the subject resulting from participation in the research;
  (d) Approximate number of subjects involved in the study.

• Use of authorized signature lines in addition to subject lines on the consent form may be required depending on the nature of the study and the types of subjects you plan to use. If a subject is represented by an individual (proxy) to make medical and/or research decisions this person would then be required to sign the informed consent form. If your study will only comprise individuals who are able to consent or assent to participate then there is no need for the authorized signature line and date and no need to provide space for a description of what the authorization is based upon. As a result, the consent/assent forms for such a study would only have the participant’s signature line/date and the witness’s signature line/date.

• Audio/Video Taping

For all projects submitted to the IRB which include any form of audio recording of any portion of the research project, the following section should be included as the SECOND section of the consent (with optional areas filled in as appropriate for the proposed project). The wording should be simplified for child assents:

Is there any audio or video recording?
This section should include information related to audio or video recording if it is applicable to the project proposed. If there is audio and/or video recording, please include the following paragraph:

“This research project will include audio (and/or video if applicable) recording of (SPECIFY WHAT IS BEING RECORDED AND HOW). This audio (and/or video) recording will be available to be heard by the researcher, the IRB), any granting agencies (IF APPROPRIATE also SPECIFY which agencies), and the following (SPECIFY: such as dissertation chair or committee, other researchers, classes, or no one else or as appropriate). The recording will be transcribed by (BE
SPECIFIC, including “The recording will not be transcribed.” if no transcription will take place. The recording will be kept securely (SPECIFY WHERE AND HOW). The recording will be kept for XX months (SPECIFY) and destroyed after that time (SPECIFY HOW). Because your voice (or your image and your voice) will be potentially identifiable by anyone who hears (or hears and sees) the recording, your confidentiality for things you say (or do) on the recording cannot be guaranteed although the researcher will try to limit access to the tape as described in this paragraph.”

Frequently Asked Questions

• When are consent forms required?

Consent forms are required in all studies that collect information for or about human subjects except under the following conditions:

1. Research on a de-identified dataset (as previously defined)
2. Research on a limited dataset pursuant to a dataset agreement
3. Research or preliminary research authorized by a duly appointed privacy board
4. Research conducted using an anonymous survey to adults, where a statement about the voluntary nature of the survey is contained in the survey instructions

• Does the consent form always have to be signed?

In general, all consent forms must be signed. A copy is to be given to the subject as well after all of the signatures have been secured. Principal investigators must maintain a copy of the signed executed forms in their research records. The IRB may waive the requirement to obtain a signed consent form for some or all subjects if:

1. the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality, and
2. the research presents no more than minimal risk and involves no procedures for which written consent is normally required. In cases where documentation is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. For example, there are some surveys where the likelihood of any risk is minimal (such as a questionnaire about food preferences) and where the only information identifying the client would be the signature on the consent form. In such cases, instead of a signature line, the researcher may add at the end of the standard consent form, “I understand that my completion of this survey (or questionnaire) implies my consent to participate in this study.”

• Do I always have to use the NSU consent form format?

In general, the answer is yes; however, in cases where the study is being done in its entirety at another institution with a federally approved IRB, the researcher may request
that he or she use the form of that institution. In such cases, the researcher must submit the alternate consent form along with approval from the other IRB. Such a request will be reviewed to see that the form meets NSU requirements although in a different format. In cases where the requirements are met, the alternate consent form may be used. In other cases, the IRB may suggest alterations to bring the form into compliance, or, if this is not possible, the use of two consent forms.

- How long should I keep signed informed consent forms?

Signed consent forms should be retained in a secure file for a minimum of three (3) years from the date the study was concluded. You should note, however that some funding agencies require a longer period of time. For multi-site studies, the date of study completion may exceed the date you stop the study at your local site. The date you must use to account for the three years is the date ALL research related to the study concluded.
Assent Form Instructions – Children/Adolescents ages 7-17
Version: 04/12/2007

General instructions: Researchers should tailor the assent form to the age and developmental level of the subjects. While the adult / parental consent forms must have all categories, the child assent form may be made shorter and simpler if the child would not be able to understand the more detailed information. Use wording that is as simple as possible. Recommended wording follows. Examples and explanations are italicized.

What is a research study?

We’re asking you to be in a research study. Research is a way to help us learn new things. Only people who decide they want to help will be in the study. We’ll tell you about the study and then you should take time to make your decision. You should talk to your parents or your guardian before you decide.

Why is this study being done?

*Explain the study purpose in simple language.*

Example A. This study is to find out if the type of toothbrush you use makes a difference in how many cavities you get.

Example B. This study is to find out what type of cancer treatment works best.

Example C. This study is to find out if teaching children to relax is the best way to treat children who have been touched by adults or had sex with adults.

What will happen to me?

*Explain the methods in simple language.*

Example A. A dentist will check your teeth and fix any cavities. You’ll use one type of toothbrush for six months. The dentist will again check your teeth and fix any cavities. You’ll use a different type of toothbrush for the next six months. The dentist will check your teeth and fix any cavities one more time.

Example B. You’ll be given a second medicine while you are getting your regular cancer treatment. Half of the children will get the real study medicine and half will get a fake medicine. The fake medicine is a pill that looks like the study medicine but isn’t a real medicine. You won’t know if the pill is the real medicine or the fake medicine. Even your parents and your doctor won’t know until the study is over whether you got the real or fake medicine. The study will see if children who got the real medicine got better any faster than those who took the fake medicine.

You won’t get any extra tests because you’re in the study. The doctors will look at your medical chart and write down facts.
Example C. You’ll see a psychologist who will ask you questions about how you feel. A psychologist is a type of doctor who helps people with their feelings. The psychologist will give you one of two types of treatment to help you. It might be a treatment where you learn to relax when you think about the hurt that the adult caused you. It might instead be a treatment where you talk about your feelings without teaching you to relax. At the end of the study, the psychologist will ask you the same questions about how you feel, to see if you are feeling better.

What are the good things about being in this study?

Explain benefits. Include payment. Number the items or use bullets if there are multiple benefits. Benefits and risks can be combined into one section.

Example A  There are four good things that might happen.
  1. You may find out which type of toothbrush you like.
  2. You may get fewer cavities because of using the special toothbrushes.
  3. You’ll be given the toothbrushes, but you won’t be given anything else.
  4. Your parents won’t have to pay for you to get your teeth checked and your cavities filled.

Example B. We can’t promise you that being in this study will help you. You may get better or you may get worse. The doctors might find out if this type of medicine helps other children with your type of cancer.

Example C. You’ll get help with your feelings about how you were hurt if you are a part of this study, but we can’t promise that the help will make you get over your pain. Your parents will pay for your seeing the psychologist. They don’t get anything free if you help with the study. The psychologist might find out something that can help other children who have been hurt.

Will being in the study hurt me?

Explain risks. Number the items or use bullets if there are more than two risks.

Example A. It is possible that you might get more cavities using the new toothbrushes than if you stick with the one you use now.

Example B. Some children don’t feel good after they take the medicine. They might feel these things:
  - Upset stomach
  - Headache
  - Feel like they have a cold.
Example C. We don’t think that being in this study can hurt you. If you tell the psychologist about other people who have hurt you, the psychologist will have to tell your parents. But that is true if you are in the study or not.

How long will I be in the study?

Explain time commitment.

Example A. The study is for one year. You’ll come for two dentist check ups, which take about one hour each time. If you get cavities, you’ll come to another visit to get them filled. How long those visits take depends upon the number of cavities you have. It could take an hour each time.

Example B. You’ll be in the study for 9 months.

Example C. You’ll see the psychologist twice a week for one half hour. You’ll do this every week for five months.

Do I have other choices?

Example A. You can decide not to be in the study and use your regular toothbrush.

Example B. You can decide not to be in the study and get the regular cancer treatment without the new medicine.

Example C. If you don’t want to be in the study, you’ll still get the treatment that does not teach you to relax, and you will not answer the questions at the start and end of your treatment.

Will people know that I am in the study?

Describe confidentiality. Avoid using the word “secret”.

Example A. The people at the dentist’s office will know that you are in the study, but they won’t tell anyone else. If they talk about the study or write about it they won’t use your name.

Example B. Your regular doctor and people at the cancer treatment center will know that you are in the study. The doctors won’t use your name when they talk about the study or write about what they learned.

Example C. Only the psychologist and one person who helps the psychologist will see the questions that you answered. The psychologist won’t use your name when telling other people about the best way to help children like you.

Example of special risk statements to use if applicable:
If we learn that someone has abused (hurt) a child or an old person, we have to tell the police or other people who can make the abuse stop.

If we find that you have a disease that can be spread by having sex, like syphilis, clamidia, HIV or AIDS, we have to tell the Health Department and we have to tell your parents so that you can get medical treatment. (Note: if the study is not in the State of Florida, researchers should check applicable state law.)

If we find out that you committed a crime, we have to tell the police.

If we find out that your parents have committed a crime, we have to tell the police.

Is there anything else I should know about the study?

If there is additional information that needs to be disclosed, use this section.

Who can I ask questions?

If you have any questions you can ask _________. Remember, you should also talk with your parents or your guardian about this study.

Is it OK if I say “No, I don’t want to be in the study”? 

You do not have to be a part of this study if you don’t want to. No one will be mad or upset.

If you change your mind, you can decide during the study to stop being in the study.

If applicable add: If you do stop during the study, we will keep the information that we got while you were in the study.

Do you understand and do you want to be in the study?

I understand. All my questions were answered.

☐ I want to be in the study.
☐ I don’t want to be in the study.

_____________________________________
Your name

_____________________________________
Your signature Date

_____________________________________
Signature of person explaining the study Date
This form is intended to assist researchers in creating consent and assent forms.

Informed consent is one of the primary ethical requirements for research with human subjects; it reflects the basic principle of respect for persons. No investigator may involve a human being as a subject in research, as defined in the Nova Southeastern University Institutional Review Board policy, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted on two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e. his or her consent is voluntary.

The checklist below is provided to ensure that each of the following components is included in your consent form. The IRB also recommends reviewing the template and model information at [http://www.nova.edu/irb/manual/forms.html](http://www.nova.edu/irb/manual/forms.html)

<table>
<thead>
<tr>
<th>Component</th>
<th>Self-Checklist</th>
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<tbody>
<tr>
<td><strong>General Items</strong></td>
<td></td>
</tr>
<tr>
<td>The consent form is written in a language understandable to the subject or his/her legal representative.</td>
<td></td>
</tr>
<tr>
<td>The consent form is written in a consistent voice to describe the participants, preferably second with the exception of the Voluntary Consent section, which is written in the first person. The researcher may use the 3rd person or the 1st person to describe him/herself.</td>
<td></td>
</tr>
<tr>
<td>The first page of the consent form is on original Nova Southeastern University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable</td>
<td></td>
</tr>
<tr>
<td>The consent form contains no language through which the subject is made to waive any of his/her legal rights or which releases the investigator</td>
<td></td>
</tr>
<tr>
<td>All consent pages are numbered to reflect the current page and the total number of pages (Page X of Y) along with initial and date lines on all pages.</td>
<td></td>
</tr>
<tr>
<td><strong>Consent Form Heading Section</strong></td>
<td></td>
</tr>
<tr>
<td>The title of the study is presented in the manner requested by the IRB, for example “Consent Form for Participation in the Research Study Entitled XYZ”</td>
<td></td>
</tr>
<tr>
<td>If the research is externally funded, the funding agency is listed under funding source or there is an indication of “None” if no funding source exists.</td>
<td></td>
</tr>
<tr>
<td>Space is provided for the IRB to assign a protocol no and reads “IRB protocol #”</td>
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</table>
The name, address, and telephone number of the investigator(s) is listed, identifying those individuals who are principal investigators and those who are co-investigators. If the principal investigator is a student, the address and phone number of his/her advisor(s), clinical supervisor(s) are listed.

Site information (address) of where research data will be collected or research activities will occur with subjects if this information is different than the address of investigator/co-investigator or there are multiple sites.

Include immediately under the addresses of the investigators: For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

<table>
<thead>
<tr>
<th>Description of the Study</th>
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<tbody>
<tr>
<td><strong>(Sections - What is the study about? Why are you asking me? What will I be doing if I agree to be in the study?)</strong></td>
</tr>
<tr>
<td>A statement that the study involves research and an explanation of the purpose of the research is included. There must also be a statement that explains the purposes of the research.</td>
</tr>
<tr>
<td>A concrete description of the study procedures to be followed, including the amount of time subjects are being asked to contribute and the nature of the questions or data to be collected, is included. Any procedures that are experimental are identified and any alternative procedures disclosed. The approximate number of subjects involved in the study. Include anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent</td>
</tr>
<tr>
<td>A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject must be included.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audio or Video Recording</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Sections – Is there any audio recording? Is there any video recording?)</strong></td>
</tr>
<tr>
<td>Include audio and video tape information (if applicable) in keeping with the paragraphs provided in the model forms.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Section – What are the dangers to me?)</strong></td>
</tr>
<tr>
<td>A description of any reasonably foreseeable risks and possible discomforts and/or inconveniences to the subjects, if any, is included.</td>
</tr>
<tr>
<td>For research involving more than minimal risk, include an explanation as to whether</td>
</tr>
</tbody>
</table>
any compensation and/or any medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained. Include a statement as to who will be responsible for the costs related to medical expenses associated with research-related injuries.

Include an explanation of whom to contact for answers to questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.

**Benefits**

*(Section – Are there any benefits to me for taking part in this research study?)*

A description of any benefits to the subjects or to others that may reasonably be expected from the research is included. If no benefits are expected, this is stated.

**Compensation and/or Cost**

*(Section – Will I get paid for being in the study? Will it cost me anything?)*

If subjects will be compensated for their participation, include a statement addressing this and describing in detail the nature of the compensation and the schedule of compensation if it is prorated or dependent on completion of certain activities.

Describe any additional costs to the subject that may result from participation in the research.

**Confidentiality**

*(Section – How will you keep my information private?)*

A statement describing the extent to which confidentiality will be maintained is included in addition to a clause that states that all information obtained is strictly confidential unless disclosure is required by law. This section should also include information as to the record retention period. (NOTE: A minimum of 3 years after the study is over is required by the NSU IRB).

As a part of the confidentiality section, include a statement that the NSU-IRB and other regulatory agencies may review research records. If the principal investigator is a student, there must also be a statement that the dissertation chair/faculty adviser may review the research records.

**Academic Information**

*(Section – Use of Student/Academic Information)*

Include a statement regarding the use of information from student records if the study involves student records.

**Voluntary Consent**
### (Section - What if I want to leave the study?)

Include a statement that participation is voluntary, that refusal to join the study involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. This statement must be followed by an explanation of how data collected will be managed if a participant decides to leave (e.g., kept until the conclusion of the study, kept in perpetuity, keep but do not use, etc.). Destruction of data is not permitted. Please see the model and templates for suggested language.

### Additional Information

#### (Section – Other Considerations)

Include a statement that significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation, will be provided to the subject.

The entire Voluntary Consent section on the consent form is completed and appears as follows:

By signing below, you indicate that
- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree to participate in the study entitled “XYZ”

Followed by the appropriate signature lines as outlined below.

A space for the subject's signature and date, subject's name to be printed and date, and the signature of the person obtaining consent and date. Space is also provided for the signature of an authorized representative, date, and the basis for that representation, if applicable.

An assent form is included for subjects 7-17 years of age. This may be either a child assent, an adolescent assent, or both (depending on the age range of subjects). See model and template forms for child and adolescent assents.

Flyers, brochures, advertisements, or other recruitment materials are attached. Recruitment material must have Nova Southeastern University on them.

If the language of the consent form/assent form is other than English, a certified copy of the Informed Consent Form in that language is included with documentation.
indicating translation by a certified translator or the investigator may wait until notified by the IRB to have the consent form translated.

When appropriate, one or more of the following elements of information shall also be provided to the subject:

<table>
<thead>
<tr>
<th>A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.</td>
</tr>
</tbody>
</table>
Exceptions from Requirements for Informed Consent

DHHS Exceptions

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents:

- The research involves no more than minimal risks
- The rights and welfare of subjects will not be adversely affected
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- The research is to be conducted for the purpose of demonstrating or evaluating federal, state, or local service programs that are not research programs, etc.

FDA Exceptions

Obtaining informed consent may be waived if both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

- Subject is in a life-threatening situation necessitating use of test article
- Consent cannot be obtained because of an inability to communicate with or obtain consent from the subject
- Time is not sufficient to obtain consent from subject’s legal representative
- No alternative generally approved method is available

If immediate use of the test article is required to save the life of the subject and time is not sufficient to obtain independent determination by another physician, a determination by the investigator shall be made. This determination by the investigator is to be reviewed and evaluated by a physician who is not participating in the investigation within five (5) days after the use of article. The documentation required above must be submitted to the IRB within five (5) working days after the use of the test article.

Short Form Documentation

In most cases, the standard consent forms described under Types of Informed Consent Forms should be used, however, in some cases the IRB may authorize the use of a short form that states that the elements of informed consent have been obtained from the subject. When using the short form the following conditions must be met: The written summary of what is to be said receives prior approval of the IRB

- The witness must be present at the oral presentation
- The short form is signed by the subject or his or her representative
- The witness signs both the short form and the written summary is given to the person signing the form
- A copy of both the short form is provided along with the written summary.
Appendix C
Consent and Assent Form Document Templates and Models
The most current templates and models for consent and assent forms may be found here:

http://www.nova.edu/irb/manual/forms.html

Researchers are encouraged to review the separate guidance documents on the aforementioned page in addition to the templates and models as they develop their own consent/assent forms.

For NSU letterhead, please contact your center/college representative.
Appendix D
NSU-IRB Submission Form for Continuing Review of Approved Studies
**NSU-IRB Submission Form for Continuing Review of IRB Approved Studies**

Version: 12/2009

**Instructions:** In order to comply with federal regulations requiring **continuing review**, as well as to conform to guidelines of the university’s Institutional Review Board (IRB), the principal investigator is required to complete all of the following items for projects that will continue beyond the period of approval granted by the IRB. Continuation of a study includes data analysis, even if no further subject interaction occurs. Investigators are advised to submit this form and all necessary documents at least three months before the expiration date of the study’s approval. For further information, refer to the *Monitoring of Approved Research, Approval Duration, and Continuing Review* policy available on the IRB Web site (http://www.nova.edu/irb/manual/policies.html). Please contact your center representative for information regarding submitting this form. This form should be sent directly to the IRB Office at NSU, Office of Grants and Contracts, 3301 College Avenue, Fort Lauderdale, FL 33314, ATTN: IRB.

Please download this document and fill in the BLUE sections using a word processor. You may expand the size of sections if needed to answer the questions. Do not be concerned about where page breaks fall. Fill in all questions; if not applicable, write NA.

### I. General Information

**Project Title**

Insert Principal Investigator’s (PI) Last Name and Date of Submission in the footer.

<table>
<thead>
<tr>
<th>IRB Protocol #</th>
<th>Initial IRB Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previous Reapproval Date(s)</th>
<th>Current Continuing Review Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### II. Principal Investigator (PI) Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Relationship to NSU (Check Applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Faculty</td>
</tr>
<tr>
<td></td>
<td>Staff</td>
</tr>
<tr>
<td></td>
<td>Student</td>
</tr>
</tbody>
</table>

Mailing Address (for students)

Daytime Phone

Alternate Phone

NSU Email Address

Alternate Email Address

Principal Investigator’s Signature: ___________________________ Date: __________

If the PI is a student, the thesis adviser/dissertation chair must also sign this form.

Chair/Adviser’s Signature: ___________________________ Date: __________
### III. Status of the Research

Please provide a summary of the methods and procedures of the study.

<table>
<thead>
<tr>
<th>Please describe any new literature or findings related to the study.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Please describe any changes to the risks or benefits associated with the study.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are you seeking approval to continue to enroll new subjects?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If “Yes,” then please attach the following.

- CURRENT CONSENT FORM(S) (STAMPED).
- COPY OF CLEAN CONSENT FORM(S) FOR STAMPING.

Please see http://www.nova.edu/irb/manual/forms.html for instructions regarding consent forms.

**Please note:** If your study also requires changes/amendments please use the NSU-IRB Submission Form for Amendment of IRB Approved Studies. Amendments include, but are not
limited to, changes in funding source, number of subjects to be enrolled, methods, procedures, or the content of the consent documents or recruitment materials.

### IV. Subject/Participant Information and Study Timelines

#### Types of Subjects/Participants (complete all that apply)

<table>
<thead>
<tr>
<th>Types of Subjects/Participants</th>
<th>Fetus/abortuses</th>
<th>Newborns/Infants</th>
<th>Children (2-7)</th>
<th>Children (8-12)</th>
<th>Adolescents (13-17)</th>
<th>Adults (18+)</th>
<th>Pregnant Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # Originally Approved</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Entered in Study to Date*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Of Screen Failures**</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td># Completing Study to Date</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Who Withdrew</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># to Enroll in the Future***</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

*By Entered the IRB means any subjects who consented to participate in the study and began study activities.
**By Screen Failure the IRB means individuals who signed the consent form, but later proved not to qualify for the study during screening procedures.
***Please remember that your future number of subjects cannot exceed the total number of subjects originally approved by the IRB. If you need to exceed that number, please submit an amendment as well.

Please provide a detailed description as to why the subjects withdrew or were withdrawn.

Anticipated end date of subject recruitment

Anticipated end date of subject participation

Anticipated end date of data analysis and interpretation

### V. Changes

Please describe below any substantive amendments since the protocol was initially and approved by the IRB.

### VI. Summary of Results to Date

Please describe significant findings to date in the box below.
### VII. Participant Complaints

Were there any complaints from subjects?  

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**If “Yes,” please provide a detailed description of the subjects’ complaint(s). If more than one subject complained, please provide the information by subject. For example, “Subject 1: Nature of complaint. Nature of resolution.”**

Is this study multi-site?  

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If “Yes,” please attach any related reports from the other sites.

### VIII. Unanticipated Problems/Adverse Events

List ALL adverse events or unanticipated problems (for multi-center studies, from NSU researchers only) and their resolution. (If none, state none). Attach copies of all adverse reaction reports, even if previously reported.

**Unexpected/Adverse Reaction and Resolutions**

Do the results of the study to date suggest that the study risks differ from what was originally described in the research submission?  

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**If “Yes,” please describe.**

### IX. Consent Forms

Are you seeking approval to continue to enroll new subjects?  

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**If “Yes,” then please review and complete the following.**

ATTACH CURRENT CONSENT FORM(S) (STAMPED)  
ATTACH CLEAN CONSENT FORM(S) FOR STAMPING

Please see [http://www.nova.edu/irb/manual/forms.html](http://www.nova.edu/irb/manual/forms.html) for instructions regarding consent forms.

**Please note:** If your study also requires changes/amendments please use the NSU-IRB Submission Form for Amendment of IRB Approved Studies. Amendments include, but are not limited to, changes in funding source, number of subjects to be enrolled, methods, procedures, or the content of the consent documents or recruitment materials.
As IRB and legal requirements continually evolve, all consent forms must be reviewed using current IRB guidelines as found on the IRB website. Have you reviewed and confirmed that the attached consent forms have been modified as necessary to meet current IRB guidelines.

If “No,” please explain (e.g., requirement of grantor, the study is conducted at another site and their consent forms are used, or other reason).

Did the consent forms require translation?

If “Yes,” please attach the original English version along with all translations, and submit the consent forms to be used during the study continuation.

<table>
<thead>
<tr>
<th>X. Recruitment Materials</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you continuing to recruit subjects?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Are you using flyers or other recruitment materials to continue to recruit?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Please attach the most current recruitment materials. Please include a copy of the previously approved (and stamped) materials and a clean unstamped version.
Appendix E
NSU-IRB Submission Form for Amendment of Approved Studies
**NSU-IRB Submission Form for Amendment of IRB Approved Studies**

**Version:** 12/2009

**Instructions:** Federal regulations and NSU policy require researchers to obtain approval for study modifications before implementing changes to approved research. If your original study submission approval was at the center level (exempt determination), then submit this form to your center representative. If it was approved after expedited or full board review, then please submit the form directly to the IRB office (NSU, Office of Grants and Contracts, 3301 College Avenue, Fort Lauderdale, FL 33314, ATTN: IRB). For further information, refer to the Amendments to Research policy on the IRB Web site http://www.nova.edu/irb/manual/policies.html. Please contact your center representative or the IRB administrator (954-262-5311) if you have questions.

Please download this document and fill in the BLUE sections using a word processor. You may expand the size of sections if needed to answer the questions. Do not be concerned about where page breaks fall.

### I. General Information

<table>
<thead>
<tr>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Insert Principal Investigator’s (PI) Last Name and Date of Submission in the footer.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IRB Protocol #</th>
<th>Initial IRB Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>

### II. Principal Investigator (PI) Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Relationship to NSU (Check Applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[ ] Faculty</td>
</tr>
<tr>
<td></td>
<td>[ ] Staff</td>
</tr>
<tr>
<td></td>
<td>[ ] Student</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mailing Address (for students)</th>
<th>Faculty</th>
</tr>
</thead>
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<tr>
<td>[ ]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Daytime Phone</th>
<th>NSU Center/College/Dept</th>
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<table>
<thead>
<tr>
<th>Alternate Phone</th>
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</table>

<table>
<thead>
<tr>
<th>NSU Email Address</th>
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<table>
<thead>
<tr>
<th>Alternate Email Address</th>
</tr>
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<tbody>
<tr>
<td>[ ]</td>
</tr>
</tbody>
</table>

| Principal Investigator’s Signature: ____________________________ Date: _______ |
| [ ]                                                                      |

If the PI is a student, the thesis adviser/dissertation chair must also sign this form.

| Chair/Adviser's Signature: ____________________________ Date: _______ |
| [ ]                                                                      |
### III. Prior Approved Changes

Had you previously requested study changes since the study was approved initially?

| Yes | No |
--- | --- |

If “Yes,” please list those changes in the box below. (You may be asked for a revised protocol if the study has changed significantly since the initial review as a result of the combined past and proposed changes. You may submit a copy of the revised protocol, following the same format as the original submission, if you believe it will be helpful.)

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
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</table>

### III. Summarize the Current Study Protocol and Your Proposed Changes

If your study was approved at the Center level (exempt), then submit the original protocol. If your study was reviewed at the expedited or full review levels, the original submission is on file, so you do not need to submit another copy. Your summary of the study should be sufficient to allow the reviewer to understand the significance of the proposed changes.

<table>
<thead>
<tr>
<th>Current Study Protocol</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Proposed Changes</th>
</tr>
</thead>
</table>

### IV. Consent Forms and Recruitment Materials

Do the proposed study changes require any modification to the consent/assent forms or to recruitment materials?

| Yes | No |
--- | --- |

If “Yes,” please explain the changes made to the consent/assent forms and include a copy of the revised forms. Please use the most recent consent form template (see [http://www.nova.edu/irb/manual/forms.html](http://www.nova.edu/irb/manual/forms.html)).
Appendix F
NSU-IRB Closing Report Form
**NSU-IRB Closing Report Form for IRB Approved Studies**  
Version 12/2009

**Instructions:** This form is to be completed for all studies approved via expedited or full review procedures. The form must be submitted within 30 days of the conclusion of research activities (intervention/interaction with human subjects AND data analysis have ended). This form should be sent directly to the IRB Office at NSU, Office of Grants and Contracts, 3301 College Avenue, Fort Lauderdale, FL 33314, ATTN: IRB.

Please download this document and fill in the BLUE sections using a word processor. You may expand the size of sections if needed to answer the questions. Do not be concerned about where page breaks fall. Fill in all questions; if not applicable, write NA.

### I. General Information

**Project Title**

Insert Principal Investigator’s (PI) Last Name and Date of Submission in the footer.

<table>
<thead>
<tr>
<th>IRB Protocol #</th>
<th>Initial IRB Approval Date</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previous Reapproval Date(s)</th>
<th>Current Continuing Review Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### II. Principal Investigator (PI) Information

**Name**

**Relationship to NSU (Check Applicable)**

- Faculty
- Staff
- Student

**Mailing Address (for students)**

**Daytime Phone**

**Alternate Phone**

**NSU Email Address**

**Alternate Email Address**

**Principal Investigator’s Signature:** ___________________________  
**Date:** ________________

82
### III. Subject/Participant Information and Study Timelines

**Types of Subjects/Participants (complete all that apply)**

<table>
<thead>
<tr>
<th></th>
<th>Fetus/abortuses</th>
<th>Newborns/Infants</th>
<th>Children (2-7)</th>
<th>Children (8-12)</th>
<th>Adolescents (13-17)</th>
<th>Adults (18+)</th>
<th>Pregnant Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # Originally Approved</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Entered in Study to Date*</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td># Of Screen Failures**</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Completing Study to Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Who Withdrew</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*By Entered the IRB means any subjects who consented to participate in the study.
**By Screen Failure the IRB means an individual who signed the consent form, but later proves not to qualify for the study during screening procedures.

Please provide a detailed description as to why the subjects withdrew or were withdrawn.

### IV. Summary

Please briefly describe in a non-technical manner the purpose of the research.

Please briefly describe any findings.

### V. Participant Complaints

Were there any complaints from subjects?  

If “Yes,” please provide a detailed description of the subjects’ complaint(s). If more than one subject complained, please provide the information by subject. For example, “Subject 1: Nature of complaint. Nature of resolution.”

Is this study multi-site?  

If “Yes,” please attach any related reports from the other sites.
### VI. Unanticipated Problems/Adverse Events

List ALL adverse events or unanticipated problems (for multi-center studies, from NSU researchers only) and their resolution. (If none, state none). Attach copies of all adverse reaction reports, even if previously reported.

<table>
<thead>
<tr>
<th>Unexpected/Adverse Reaction and Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Do the results of the study to date suggest that the study risks differ from what was originally described in the research submission?

- [ ] Yes
- [ ] No

**If “Yes,” please describe.**

<p>| |</p>
<table>
<thead>
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Appendix G
HIPAA Related Documents
Effective December 10, 2009 the NSU IRB approved proposed policies and forms created by the NSU Office of Corporate Compliance. Principal investigators are advised to review the following on the NSU IRB Web site (http://www.nova.edu/irb/manual/policies.html and http://www.nova.edu/irb/manual/forms.html):

HIPAA Policies

- HIPAA Research Policy No. 1: General
- HIPAA Research Policy No. 2: IRB Waiver of HIPAA Authorization
- HIPAA Research Policy No. 3: De-identified and Decedent Information
- HIPAA Research Policy No. 4: Reviews Preparatory to Research
- HIPAA Research Policy No. 5: Accounting of Disclosure
- HIPAA Research Policy No. 6: Guidance on Research at Outside Entities

HIPAA Forms and Instructions

- Authorization Form (only a heading, the 2nd indented link should be the actual link to the model form)
  - NSU Authorization for Use and Disclosure of Protected Health Information in Research (Exhibit 1)
  - Instructions for Preparing the Authorization For Use and Disclosure of Protected Health Information in Research Form (Exhibit 2)
- Notice of Privacy Practices (Exhibit 3a)
- Acknowledgement of Receipt of Notice of Privacy Practices (Exhibit 3b)
- Documentation of Good Faith Efforts (Exhibit 4)
- IRB Guidance on Research versus Educational Activity (Exhibit 5)
- NSU HIPAA Authorization for Educational and Related Purposes (Exhibit 6)
- Accounting of Disclosures for Research (Exhibit 7)
- IRB Waiver of Authorization Form (Exhibit 8)
- IRB Research on Decedent’s Information Without Authorization Form (Exhibit 9)
- IRB Review Preparatory to Research Form (Clinic Workforce Version) (Exhibit 10)
- IRB Review Preparatory to Research Form (NSU Affiliate-Outside Researcher Version) (Exhibit 11)
- IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version)—Request for IRB to Waive Patient Authorization (Exhibit 12)
- 42 CFR Part 2 Addendum Form (Exhibit 13)
- HIV Records Addendum Form (Exhibit 14)
- Mental Health Records Addendum Form (Exhibit 15)
Appendix H
Unanticipated Problem and Adverse Event Report Form
Nova Southeastern University
Institutional Review Board for Research with Human Subjects (IRB)
Unanticipated Problem and Adverse Event Report

Please review the IRB’s policy on Unanticipated Problems and Adverse Events found at (http://www.nova.edu/irb/manual/policies.html).

<table>
<thead>
<tr>
<th>Date of this Report:</th>
<th>IRB Protocol #:</th>
<th>NSU Center/College:</th>
</tr>
</thead>
</table>

Project Title

Principal Investigator Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Relationship to NSU:</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Faculty □</td>
</tr>
<tr>
<td></td>
<td>Staff □</td>
</tr>
<tr>
<td></td>
<td>Student □</td>
</tr>
</tbody>
</table>

| Home Mailing Address (for students) | |
| City/State/Zip: | |
| Office Phone: | Home Phone (for students): |
| Email: | |

Study Sponsor:

Has the sponsor been notified? Yes □ No □
Date of Notification:

Unanticipated Problem/Adverse Event Information
Submit 1 Adverse Event Report for each subject. You may use additional sheets to describe the nature of the adverse event. If a separate notification is required for sponsored studies and/or regulatory agencies, please include a copy of that notification.

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Date of Adverse Event</th>
<th>Description of Unanticipated Problem/Adverse Event</th>
<th>NSU Subject? Yes □ No □</th>
</tr>
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</table>

Was the Adverse Event Serious? Yes □ No □
Was the Adverse Event Unexpected? Yes □ No □
Was the Adverse Event Unanticipated? Yes □ No □
Study Related Adverse Event? Yes □ No □

Should the protocol and/or consent forms be revised Yes □ No □
If Yes, please submit a copy of the corrected amendment forms with **bold** changes and a clean copy incorporating the changes.

Will additional information be given to enrolled subjects? Yes □ No □

Principal Investigator’s Signature: ___________________________ Date: __________
<table>
<thead>
<tr>
<th>Date</th>
<th>IRB Protocol #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>NSU Center/ College</td>
</tr>
</tbody>
</table>

**Project Title**

______________________________________________________________________

**Study Sponsor**

______________________________________________________________________

**IND Safety Report dated**

______________________________________________________________________

**Serious Adverse Event / Sentinel Event Information**

<table>
<thead>
<tr>
<th>Description of Serious or Sentinel Event</th>
<th>Date of event</th>
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I have personally reviewed the IND safety report of a serious adverse event

Principal Investigator

Date
DEFINITIONS:

1. Unanticipated Problems are considered to include any incident, experience, or outcome that meets all of the following criteria:
   - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related outcomes, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
   - Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
   - Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

2. Adverse Events are any unanticipated problems involving risks to subjects or others that do not fall into the different categories under Serious Adverse Events (SAEs). For example:
   - Breach in confidentiality that may present a risk to a subject.
   - A participant’s complaint of an unanticipated risk that cannot be resolved by the research staff
   - Change to the research protocol that may result in unanticipated risks
   - Rash

3. Serious Adverse Events are defined as follows:
   - Cancer
   - Death
   - Congenital Anomaly/Birth Defect
   - Hospitalization Required
   - Life Threatening Event
   - Overdose
   - Significant or Persistent Disability/Incapacity

4. Sentinel Events defined by HRPP are:
   - Death
   - Major permanent loss
   - Permanent loss of physical or psychological function not related to natural course of subject’s illness or underlying condition

IND Safety reports are generated when a serious adverse event which may be related to the study drug and not expected occurs in any protocol using the study drug.
Appendix I
Glossary of Terms
Glossary of Terms

Assent
A child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

Assurance
A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

Authorized Institutional Official
An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

Center Level Review
Review of proposed research by a member of the Board to determine if the study is exempt from further review via either Expedited or Full Review.

Children
Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Contract
An agreement, as used here, that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant.

DHHS
Department of Health and Human Services

Expedited Review
Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Full Board Review
Review of proposed research at a convened meeting at which one more than half or the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
Grant
Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

Human Subjects
Individuals whose physiologic or behavioral characteristics, or whose understanding of their lived experiences and responses are the object of study of a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Informed Consent
A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a research-based diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Institutional Review Board (IRB)
A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Legally authorized representative
An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Linkage
Review of patient records can only be considered exempt if the subjects cannot be linked to the information collected. This means that an investigator must not maintain any form of linkage in order to go back and review the record at a later time. If linkage between the data and the subject must be maintained, the protocol should be submitted for review.

Minimal Risk
A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. The risk of completing an anonymous opinion survey about a neutral topic is no greater than the risk of other daily activities.
Office of Human Research Protections (OHRP)
The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

Principal Investigator
The scientist or scholar with responsibility for the design and conduct of a research project.

Protocol
The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Research
A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Risk
The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. (See Minimal Risk)